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INCREASING COLORECTAL CANCER SCREENING RATES IN SHELBY COUNTY, TENNESSEE THROUGH THE IMPLEMENTATION OF FLU-FIT IN COMMUNITY CLINICS AND PHARMACIES

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CAPSTONE PROJECT PAPER

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Project Abstract/Summary

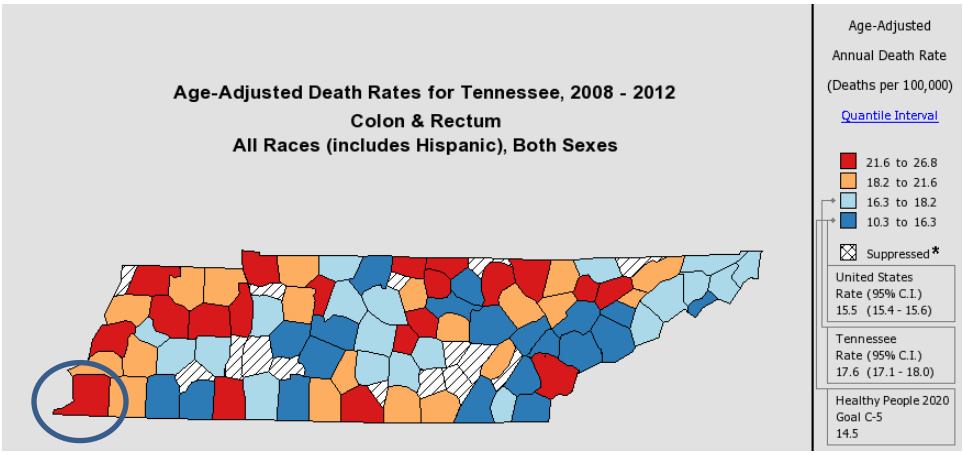
The Shelby County Health Department (SCHD) proposes implementing of Flu-FIT in community clinics and pharmacies to increase colorectal cancer screening (CRCS) rates in Shelby County, Tennessee. Flu-FIT is an evidenced-based program that involves health care providers offering patients between 50 and 75 years of age the fecal-immunochemical test at the time the patients receive their annual influenza vaccine along with counseling on colorectal cancer and reminder phone calls. Flu-FIT aligns with the mission of SCHD to "promote, protect, and improve the health and environment of all Shelby County residents." The project's short term outcomes include increasing CRCS rates in patients that receive the flu shot; improving patient's knowledge of CRCS; navigation of patients with a positive FIT result to a colonoscopy; and developing sustainable workflow processes for implementation. The project's long term outcomes include increasing CRCS rates in the county, increasing CRCS adherence, acceptance of Flu-FIT as a standard of care by health care providers, and ultimately decreased colorectal cancer mortality and incidence in the county. Under the leadership of Cara Nunnally, the Director of Health Planning and Promotion at the SCHD, the department will partner with Christ Community Health clinics, Baptist Medical Group clinics, and Walgreens pharmacies and their nurses, pharmacists, and pharmacy interns to reach patients eligible for CRCS. In addition, several local community representatives will contribute to the planning and implementation of Flu-FIT. All project activities are linked with an extensive evaluation plan. The results and lessons learned from this project will be shared at various conferences to reach public health professionals. Proposed conferences include the CDC Cancer Survivorship Conference, American Public Health Association Conference, and/or the American Association for Cancer Education Conference. Findings will be shared with other health care providers at the Memphis Physicians Association annual meeting, Tennessee Nurses Association (TNA) annual meeting, and the Tennessee Pharmacists Association (TPhA) annual meeting.

Target Population and Need

Colorectal Cancer Mortality

Colorectal cancer is the third most commonly diagnosed cancer and the second leading cause of cancer death in both men and women in the US. The American Cancer Society (ACS) estimates that each year 50,310 people die from colorectal cancer in the US.[1] In Tennessee, the mortality rate for colorectal cancer was 17.2 per 100,000 from 2008 to 2012,[2] about 10% higher than the US rate at 15.5 per 100,000.[3] The figure below (**Figure 1**), from National Cancer Institute's State Cancer Profiles, shows that colorectal cancer mortality rates vary geographically within the state.[4]

Figure 1. Age Adjusted Colon Cancer Death Rates for Tennessee



In **Figure 1**, the circled region is Shelby County. Memphis is the county seat of Shelby County and the largest city in the state, inhabited by about 12,847 more people than Nashville.[5] Shelby County has among the highest colorectal cancer mortality rates in Tennessee at 22.6 per 100,000 from 2008 to 2012, nearly 50% higher than the US mortality rate.[2] Additionally, the incidence of colorectal cancer in Shelby County from 2008 to 2012 was only 11% greater than

the US incidence (46.7 per 100,000 vs 41.9 per 100,000) which may suggest under-screening.[6] The mortality rate in Shelby County is particularly concerning compared to other metropolitan counties in Tennessee. A 2011 report developed by the Tennessee Department of Public Health evaluating chronic diseases across the state found that Shelby County ranked highest for cancer mortality of the six metropolitan counties in Tennessee from 2004 to 2008 (Davidson, Hamilton, Knox, Madison, Shelby, Sullivan).[7] Per State Cancer Profiles, Shelby County continued to lead with the highest colorectal cancer mortality of all metro counties from 2008 to 2012.[8] There are also racial disparities in colorectal cancer incidence and mortality. From 2008 to 2012, black men and women in Shelby County had higher incidence (53.4 per 100,000 vs 40.7 per 100,000) and mortality for colorectal cancer (29.5 per 100,000 vs 16.7 per 100,000) than their Caucasian counterparts.[6,8] Following national trend, males in Shelby County had higher incidence (55.8 per 100,000 vs 40.2 per 100,000) and mortality rates (26.2 per 100,000 vs 18.6 per 100,000) for colorectal cancer than women.[6,8]

Risk Factors for Colorectal Cancer

Non-modifiable risk factors for colorectal cancer include being over 50 years of age, having inflammatory bowel disease, and having a genetic syndrome (familial adenomatous polyposis or Lynch syndrome). Lifestyle factors that may contribute to an increased risk of colorectal cancer include a sedentary lifestyle, low fruit and vegetable intake, a low fiber and high fat diet, overweight and obesity, alcohol consumption, and tobacco use.[9] According to the 2014 Shelby County Community Health assessment and the Behavioral Risk Factor Survey System (BRFSS), physical inactivity was higher in Shelby County (29.3%) than in the US (23.4%). Of the respondents from Shelby County, 73.3% did not consume adequate fruits and

vegetables (vs US 75.8%), 11% reported heavy alcohol consumption (vs US 15%), and 37.7% were former or current smokers (vs US 42.9%).[10]

Colorectal Cancer Screening

The prognosis for patients with colorectal cancer is greatly impacted by the extent of disease at the time of diagnosis (**Table 1**), emphasizing the importance of adhering to the screening schedule recommended by the U.S. Preventive Services Task Force (**Table 2**).

Table 1: Stage at Diagnosis and Associated 5 Year Survival Rate[11]

Stage at Diagnosis	5 year Survival Rate
Local	90%
Regional	70%
Distant	13%

Table 2: Recommended Screening Options and Schedule for General Population[12]

Starting at age 50 and continuing through age 75:

Screening Test	Schedule	Home test	Preparation required	Removes polyps/cancer
High-sensitivity fecal occult blood test (FOBT)	Annually	Yes	Yes	No
Fecal immunochemical test (FIT)	Annually	Yes	No	No
Flexible sigmoidoscopy	Every five years, with FOBT every three years	No	Yes	No
Colonoscopy	Every 10 years	No	Yes	Yes

The least invasive screening options for colorectal cancer are the high-sensitivity fecal occult blood test (FOBT) and the fecal immunochemical test (FIT). The FOBT uses a chemical called guaiac to detect blood in the stool, while the FIT uses antibodies. Both the FOBT and the FIT may be self-administered at home. The patient uses a stick or a brush to obtain a small

amount of stool which is then applied to a card. This is done for two separate bowel movements. The test kit is them returned to a lab where the results are read. If the results are abnormal (positive for blood), the patient must have a follow-up colonoscopy to investigate further. The major difference between these two tests is that the FOBT requires the patient to make dietary changes for the duration of the test due to the guaiac; dietary changes are not necessary with the FIT.[13] In clinical trials, the FIT was shown to have an 87% sensitivity for colorectal cancer and demonstrated 98% specificity.[14,15] Up to 20% reductions in colorectal cancer mortality have been reported for FIT-based screening programs.[16]

Both the flexible sigmoidoscopy and colonoscopy are more invasive. Both of these tests require bowel preparation, meaning that the patient must consume a clear liquid diet 24 hours prior to the test and ingest a laxative to completely empty the bowels the evening before the test.[12] For the flexible sigmoidoscopy, the physician inserts a short, thin, flexible lighted tube in the patient's rectum. This allows the physician to check for polyps (precancerous growths) or cancer inside the rectum and the lower third of the colon. Polyps and cancer cannot be removed via flexible sigmoidoscopy. For a colonoscopy, a physician inserts longer lighted tube to check inside the entire colon. During a colonoscopy, the physician can effectively remove polyps (precancerous growths) and some cancers.[13] Colonoscopies reduce colorectal cancer mortality by 60%.[17] Since colonoscopies can remove precancerous growths, colonscopies can decrease both the mortality and incidence of colorectal cancer. Colonoscopies are used as a follow-up test for any unusual results found during one of the other screening tests (FOBT, FIT, flexible sigmoidoscopy).

Colorectal Cancer Screening (CRCS) in Shelby County

According to the 2014 Shelby County Community Health Assessment, 55.1% of Shelby County respondents reported having had a FIT or FOBT within the past year, colonoscopy within the previous 10 years, or sigmoidoscopy within the previous 5 years with FOBT within the previous 3 years.[10] This CRCS rate is well below the Healthy People 2020 goal of 70.5%.[18] Other metropolitan counties of comparable size to Shelby County (Davidson: county seat Nashville; Knox: county seat Knoxville) have achieved or exceeded the Healthy People 2020 goal.[19,20]

Barriers to adhering to the annual FOBT/FIT screening schedule that have been cited include fear, lack of provider recommendation, fatalism, and not setting the priority of time for doing the test.[21,22,23,24] Less educated individuals, uninsured individuals, members of ethnic/racial minorities, and foreign-born individuals are less likely to participate in colorectal cancer screening (CRCS).[25] According to the 2012 BRFSS, of the US respondents aged 50-75 years that have *never* been screened for colorectal cancer, 76% were insured.[26] Beliefs about the benefits of screening and the barriers to completing CRCS are key predictors of participation; individuals are more likely to participate in CRCS if they do not perceive large barriers to screening and believe in the benefits of screening.[27] Additionally, patients who receive a preventive health examination are much more likely to adhere to FIT or FOBT screening than patients who do not; physicians may be more likely to recognize that a FIT or FOBT is due and counsel patients on barriers to adherence or alternative methods of CRCS.[28]

Resources in Shelby County for Implementation of Colorectal Screening Program

Currently, there are no existing programs for increasing CRCS rates in Shelby County. The Shelby County Health Department (SCHD) proposes implementing Flu-FIT in Shelby

County to increase CRCS rates. Flu-FIT is an evidence-based intervention that involves healthcare providers (i.e. physicians, nurses, pharmacists) offering the FIT test with the administration of the annual influenza vaccine to eligible patients over 50 years of age in various health care settings.[29] This program has great potential to increase CRCS rates and adherence to annual FIT screening in Memphis, TN. Additional details on the Flu-FIT program will be described in the **Program Approach** section. Shelby County has several resources available to implement a CRCS program like Flu-FIT, as shown in **Table 3**.

Table 3: Resources in Shelby County

Resource	Description	Role
American Cancer Society[30]	Nationwide, community-based, voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives and diminishing suffering from cancer, through research, education, advocacy and service.	Serve as promotion for the program Potential funding source
Christ Community Health Center[31]	One of the largest Christian health centers in the nation and the largest primary healthcare provider in Shelby County. Focused on providing care to underserved populations in Memphis.	Serve as a community health center setting for the Flu-FIT program (5 clinics) Provide nurses and potential medical director
Shelby County Health Department[32]	Mission is to promote, protect, and improve the health and environment of all Shelby County residents	Serve as leader of Flu-FIT program
LocalCares[33]	Local news station	Serve as promotion for the program
Baptist Medical Group Primary Care and Walk-in Clinics[34]	Provides flu shots and primary care Mid-South's largest integrated not-for-profit multispecialty physician practice Patient information tied to Baptist Memorial Health Care System (**integrated health delivery system)**	Serve as a primary care clinic setting for Flu-FIT program. Tied to an integrated health delivery system. 3 walk-in primary care clinic locations in Memphis
Dr. Phillip Bowden[35]	Local gastroenterologist that partnered with the mayor of Memphis in a campaign to promote CRCS in 2015.	Physician's office may serve as a setting to provide follow-up colonoscopies for patients with positive FIT results Serve as a funding source
A C Wharton[35]	Former mayor of Memphis (2009-2015), partnered with Dr. Phillip Bowden in campaign to promote CRCS	Provide insight on local community Serve as promotion for the program
Walgreens Pharmacy[36]	Largest retail pharmacy chain in the US Prioritizes expansion of health and wellness services	Serve as a pharmacy setting for the Flu-FIT program (seven 24 hour locations) Provide pharmacists and pharmacy interns
Local Churches		Provide input on community concerns Serve as a promotion for the program

The Flu-FIT program was originally piloted in San Francisco and successfully implemented in health department primary care clinics, community health centers, high volume

flu clinic events through an integrated health delivery system, and retail pharmacies. Shelby County has the appropriate resources for the Flu-FIT program—community health centers, retail pharmacies, and primary care clinics tied to an integrated health delivery system—and additional resources for expanded promotion/recruitment through LocalCares and the ACS. The initiative to increase CRCS in Memphis is already supported by local gastroenterologist Dr. Philip Bowden and former Mayor of Memphis A.C. Wharton.[35]

Community Needs Assessment

Community needs and resources were identified through the 2014 Shelby County Community Health Assessment.[10] Community members identified cancer as one of the top 10 concerns for Shelby County.[37] During the planning phase of the Flu-FIT program, community members will be recruited at Christ Community Health Clinics, Walgreens pharmacies, and Baptist Medical Group clinics for participation in focus groups to gain insight on the barriers to CRCS in Shelby County. In addition, selected community members will serve in the Community Advisory Group (CAG) to provide insight on the changing needs and resources throughout the program *development* process. The CAG will be consulted on a semi-annual basis for additional insight during the *implementation* of the Flu-FIT program and updated quarterly via email on the progress of the program.

Alignment with Community Resources and Needs

Due to the need for increased CRCS in Shelby County and the wide array of available resources, Flu-FIT is expected to successfully increase CRCS in this community. Our approach with Flu-FIT is aimed at reaching all eligible individuals (including low-income, minorities, uninsured) through the utilization of diverse settings. Flu-FIT will be led by the Shelby County Health Department (SCHD), in partnership and collaboration with Christ Community Health

(CCH), Walgreens, and Baptist Medical Group (BMG). Additional partners serving in the CAG, including local non-profit organizations, institutions, Dr. Phillip Bowden, and former Mayor A.C. Wharton are listed are listed in **Appendix A**. The implementation of Flu-FIT in Shelby County will utilize every setting type that the original program utilized to maximize the number of individuals impacted, except the health department primary care clinics, which Shelby County lacks. Shelby County has health department clinics dedicated to immunizations exclusively, however this setting was not studied and proper follow-up with a primary care physician would be less likely. Additional settings may be added in the future. Extensive recruitment for this program is not necessary since Flu-FIT is targeted at individuals that are vaccinated against influenza annually. Older individuals who are vaccinated against influenza one season tend to be vaccinated in the following season,[38] therefore, greater than 80% retention is expected. Additional promotion and education on annual influenza vaccination could further increase participants.

Potential Impact

From 2014 to 2015, 222,604 individuals in Shelby County were 50-75 years old,[39] about 23% of the population. According to the 2014 Shelby County Community Health Assessment, 55.1% of eligible individuals have had a FIT/FOBT in the past year, a colonoscopy in the past 10 years, or sigmoidoscopy within the previous 5 years with FOBT within the previous 3 years.[10] Therefore, an estimated 99,949 eligible individuals (44.9%) in Shelby County did not screen for colorectal cancer and/or are not up-to-date with CRCS recommendations. This is likely an underestimation, since the 55.1% does not account for the number of individuals that are *adherent* to the annual FIT/FOBT. From 2014 to 2015, the influenza vaccination rate was 49.1% for Tennessee residents between 50 and 64 years of age.[40] According to the Shelby County

Community Health Assessment, 69% of individuals over age 65 receive the annual influenza vaccine. Therefore, roughly 111,524 to 153,596 individuals aged 50 to 75 years are estimated to receive their annual influenza vaccine.

Table 4. Patients offered FIT without influenza vaccine promotion

Setting	# patients served (all ages)	# patients 50-75yo served	# patients 50-75 yo vaccinated[A]	Expected impact[U]
Baptist Medical Group Primary Care and Walk-in Clinics (3 locations)	5,000 patients*	2,500 patients (50%)[P]	1,725 patients	774 patients
Walgreens Pharmacy (6 locations)	109,384 scripts per year per location** ~1823 patients per location x 6 10,938 patients total	5469 patients aged 50-75 years old (50% of total patients)[M]	3,774 patients	1,694 patients
Christ Community Health (5 locations)	43,114 patients served (across 5 locations)***	12,934 patients aged 50 to 75 years old (30% of total patients)[H]	8,924 patients	4,006 patients
			14,423 patients aged 50-75 yo vaccinated	**6,474 patients total offered FIT**

[A] Assuming 69% adherence per health assessment
* Estimation
[P] Assuming 50% of primary care patients are 50 and older. Per National Center for Health Statistics, adults aged 45 and older account for 57% of physician office visits.[41] Value lowered to 50% for conservative estimate for adults aged 50 to 75 years.
** Assuming 300 scripts per day and each patient fills 60 scripts per year (5 prescriptions every month)[42]
[M] 30% determined since older adults (<65) tend to contribute a greater portion to medication use, about 34% (Centers for Disease Control and Prevention and The Merck Company Foundation. "The State of Health and Aging in America 2004). This value was lowered to 30% to account for the 50-64 year old patients
*** Per HRSA profile for Christ Community Health site.[43] Assuming that 1 in14 patients use a HRSA funded health center (HRSA factsheet 2015).[44] Christ Community Health Services is the major HRSA funded health center in Shelby County[43]
[H] 30% of patients that use a HRSA funded health center are 45 years of age or older.[43] This value was used as a rough estimation.
[U]Assuming that 55.1% of patients are already up-to-date with CRCS[10]

Per the estimations in **Table 4**, 6,474 patients are expected to be eligible for and offered the FIT test through Flu-FIT without additional promotion. According to data from the Flu-FIT pilot, Potter et al reported that of the patients served that were not up-to-date with CRCS, 62% of these patients utilized and mailed the FIT.[45] At a very minimum, roughly 3,876 Memphis patients are expected to utilize and mail the FIT every year. This is a minimum because patients that are up-to-date with the annual FIT/FOBT may opt to obtain their annual FIT through Flu-FIT for that given year.

Program Approach

Flu-FIT

The program chosen by the Shelby County Health Department (SCHD) to increase CRCS in Shelby County is **Flu-FIT,** which is recognized as a Research-Tested Intervention Program.[29] In addition, Flu-FIT has been evaluated on criteria from the RE-AIM (Reach, effectiveness, Adoption, Implementation) framework, with 86.7% for Reach, 66.7% for Effectiveness, 82.2% Adoption, and 71.4% for Implementation.[46] The American Cancer Society (ACS) has worked with Dr. Potter to develop an implementation guide.[47] This program involves offering the FIT (or FOBT) to eligible patients at the time of their annual influenza vaccination in various settings. Through Flu-FIT, health care providers are able to convey the importance of annual screening and annual influenza vaccination. This program was piloted in San Francisco in 6 primary care clinics operated by the San Francisco health department,[45] drop-in vaccination clinics tied to an integrated health delivery system,[48] and 18 retail pharmacies.[49] A diverse patient population was served. The advantage of Flu-FIT (offering a FIT test with the annual influenza vaccine) is the simplicity; Flu-FIT is highly adaptable to a wide variety of settings and population sizes.

Table 5: Summary of Flu-FIT study results

Practice Setting	Results
Community-based adult primary care clinics[45]	40% increase in number of patients completing any CRCS test
Retail pharmacies[49]	59.3% of Flu-FIT participants reported completing or scheduling a CRCS test since enrollment 14.8% of CRCS education only participants reported completing or scheduling a CRCS test since enrollment
Primary care clinic tied to integrated health system[48]	29.7% of Flu-FIT participants vs 15.2% of control group completing any CRCS test within 90 days of receiving influenza vaccination

Shelby County is well equipped to implement the Flu-FIT program. The SCHD will partner with settings identified in the resource assessment (**Table 3**)—5 Christ Community Health clinics, 6 Walgreens pharmacies, 3 Baptist Medical Group primary care/walk-in clinics—for the implementation of Flu-FIT and closely follow the procedures laid out in the Flu-FIT Implementation Guide.[29] The guide offers the options of providing Flu-FIT during designated flu-clinic events or integrated with routine primary care office visits; we will be integrating Flu-FIT into routine primary care office visits.

Program Descriptions by Setting

Christ Community Health Clinics

Christ Community Health (CCH) is a one of the largest Christian health centers in the nation and the largest primary healthcare provider in Shelby County. CCH is also dedicated to providing care to underserved individuals and known for their utilization of faith-based practices (praying with patients, etc). As previously described, African-Americans have higher colorectal cancer mortality rates. Additionally, African Americans compose over half of the population in Shelby County.[50] CCH clinics will allow for increased access to the target population; several studies have found that faith based interventions are more effective for African-Americans.[51,52,53]

Five CCH clinics will be used for Flu-FIT. Each flu season (September to February), each clinic offers the influenza vaccine with each primary care visit. The new influenza vaccine is typically received during the month of September annually. During this time, other preventative services could also be offered, which provide the opportunity for clinic nurses to provide the take-home FIT test to patients eligible for CRCS.

The medical director of each clinic will provide standing orders to nurses, which allows them to provide the influenza vaccine and FITs to primary care patients between 50-75 years of age. The Flu-FIT Champion, a team member from the SCHD responsible for training and fidelity monitoring, will provide a two-hour onsite training session on the implementation of Flu-FIT (counseling, documentation, follow-up) and program evaluation (survey administration, documentation) for the nursing staff. This session also includes training on the delivery of appropriate and culturally sensitive patient education for all backgrounds and literacy levels. On the first week of September, prior to the arrival of the new annual influenza vaccine, Flu-FIT Champions will visit their assigned site to observe baseline clinic processes and patient flow and review the procedures with each nurse. During the implementation period, Flu-FIT Champions will make bi-weekly visits to each of the sites to ensure that the nurses were aware of the study procedures and to observe the implementation process. When a patient comes in for their influenza vaccine or a primary care visit, the nurse will use a screening tool (See **Appendix B**) to determine the patient's eligibility for the FIT. If the patient is eligible, the nurse will use written and/or video instructions to explain the process to the patient (**See Appendix C**). If the patient agrees, the nurse will provide the patient with the FIT and pre-paid envelopes for returning the FIT kits to QuestLabs. The nurses will document the encounter in the Flu-FIT log sheet. She will then administer the influenza vaccine. The written instructions, video instructions, and visual

aids are available in English, Cantonese, Mandarin, Russian, Spanish, and Vietnamese and with vocabulary no greater than an 8th grade level.[45] The FIT test results will be returned to the clinic from the lab and documented. Nurses will notify the primary care provider and then the patient of the result. If the FIT result is positive, the nurse will call the patient to discuss a follow-up appointment or refer the patient to a specialist per the recommendation of the primary care provider.

For the community clinic setting, Flu-FIT will follow the same processes laid out in the original study with **no major adaptations**.

Walgreens Pharmacy

Walgreens is the largest retail pharmacy chain in the US and has been known to prioritize the expansion of health and wellness services. Six Walgreens locations will be involved in Flu-FIT. These locations were selected for their business hours, either open until 10pm or 24 hours. The intention is accommodate patients with time constraints (work hours, etc). Implementation of Flu-FIT in Walgreens will also reach more insured individuals who go to the pharmacy for their annual influenza vaccine, as opposed to their primary care provider or the health department. According to 2012 BRFSS U.S. data, of the adults aged 50-75 years that never participated in colon cancer screening, 76% were insured.[26] In Tennessee, pharmacists are allowed to provide any adult immunization under the standing order of a physician, which is renewed annually.[54] For Flu-FIT, pharmacists may add the FIT test to this standing order request to the physician. Pharmacists and fourth year pharmacy interns will be responsible for administering the vaccine and the providing the FIT. Fourth year pharmacy interns are authorized to complete any pharmacist duties under the supervision of a licensed pharmacist.

During August, prior to the arrival of the annual influenza vaccine, Flu-FIT Champions will be responsible for providing on-site training on the implementation of Flu-FIT (counseling, documentation, follow-up) and program evaluation (survey administration, documentation) to the staff pharmacists and interns at their assigned pharmacy sites. This session also includes training on the delivery of appropriate and culturally sensitive patient education for all backgrounds and literacy levels. The Flu-FIT Champion will check on the pharmacies on a bi-weekly basis to ensure proper workflow and counseling and address any issues that arise. Flu-FIT implementation will begin once the influenza vaccine arrives (during September) and end February 28th. Influenza vaccination rates typically maximize around January. The existing processes for influenza vaccination will be followed, except that the pharmacist or intern will use the Flu-FIT screening tool prior to the administration of the vaccine. Eligible patients will receive a FIT, counseling and written instructions (multiple languages available, no greater than 8th grade level) on how to use the test and how to mail the test to the appropriate laboratory. Names of participating patients and the date they received the FIT will be recorded in a log. A reminder telephone call will be made to patients two weeks after the encounter, encouraging them to complete the FIT. The laboratory will send the results back to the pharmacy. If the result is negative, the intern will call the patient and his or her designated primary care provider with the result.[49] If the FIT result is positive, the patient will be notified by the pharmacist and a follow-up appointment will be arranged with their primary care provider. The pharmacist will counsel the patient on that fact that a positive FIT indicates the presence of blood in the stool, which can be caused by many factors and is not a diagnosis of cancer. A positive FIT, however, does require follow-up with a colonoscopy. The patient will be notified that the results have been

sent to their primary care provider who will discuss the next steps with them. The primary care provider will be responsible for referring the patient to a specialist.

For the implementation of Flu-FIT in Walgreens, there are some **major adaptations** with the timing of the intervention, patient counseling, and follow-up. In the pilot study, rather than implementing Flu-FIT for the entirety of flu season, Flu-FIT was only implemented during 22 specific sessions, meaning that only 22 days were dedicated to the program. However, limiting Flu-FIT to only a small portion of the flu season would severely limit the number of patients reached. Since Flu-FIT follows the existing workflow and processes for the administration of the influenza vaccine, offering the FIT and counseling eligible patients throughout the season would be feasible if the pharmacy is sufficiently staffed. The most time consuming aspect of Flu-FIT is the patient counseling involved. In the original Flu-FIT, researchers, rather than pharmacists and interns, provided the counseling on the FIT and the importance of CRCS. This may have saved some time for the pharmacists during their usual work day. Pharmacists are well equipped with the knowledge to counsel patients on the importance of CRCS,[49] and patients may be more receptive to a pharmacist that they know, rather than a member of the research team. Under the supervision of a pharmacists, fourth year pharmacy interns are also well equipped to perform these tasks. Time would be a major limiting factor for high volume locations. The pharmacist/intern-provided education will be piloted for 4 weeks, and the program will be adjusted as needed. In the original Flu-FIT, the research team was responsible for notifying the patients of their results and for making reminder calls. For our implementation of the Flu-FIT, pharmacists and interns will be responsible for following up with the patient. Currently, pharmacists and interns serve as liaisons between patients and physicians when adjusting/optimizing their medications via fax or phone. Communicating FIT/FOBT results

would be a simple adaptation using an existing system. Following up on a FIT result falls into this existing system and would also be feasible to implement.

Baptist Medical Group (BMG) Primary Care/ Walk-in Clinics

BMG is the mid-South's largest integrated not-for-profit multispecialty physician practice. There are 3 BMG Primary Care/Walk-in Clinics in Shelby County. During flu season, patients are able to walk-in to receive a flu shot with or without a primary care visit. The benefit of using this setting is that the information at BMG is tied to Baptist Memorial Health Care System, a large health system of 14 hospitals and numerous clinics, physician practices and other facilities throughout the Mid-South. The walk-in clinic was chosen to reach insured patients that want to get their flu shot with or without the primary care visit. The same processes as those used for CCH will be used for this setting. The only difference is that the patient's FIT results will be documented in the Baptist Memorial Health Care System. There are **no major adaptations** for this setting.

Adaptations Across All Settings

A minor adaptation that will be applied across all the settings is the use of the FIT test exclusively. The original Flu-FIT was also known as Flu-FOBT, because of the use of either the FIT or the FOBT home test. The FOBT is a guaiac test which requires patients to change their diets and stop taking some kinds of medication before the test.[55] The FIT test does not require this preparation and is more user-friendly.[13] -Additionally, we will also continue to offer the FIT to patients between 50 and 75 years of age that have not had a colonoscopy in the past 10 years or a FIT/FOBT in the past year, even if they do not receive a flu shot. These patients will not be included in the program specific outcome evaluation. However, we will look at screening rates across clinic settings for all CRCS eligible patients annually.

Ensuring Inclusivity Across Settings

Flu-FIT, in all of its settings, will be inclusive and non-stigmatizing toward all individuals. Each setting has existing policies to ensure proper treatment of patients, and improper treatment of patients will not be tolerated. The staff members in each setting are already accustomed to working with members of the community on a regular basis. The Flu-FIT champions will provide additional training in each setting to ensure appropriate and culturally sensitive education for patients of all backgrounds and literacy levels. The Flu-FIT Champions will make bi-weekly site visits to ensure the proper Flu-FIT implementation.

Trauma Informed Approach Across All Settings

With Flu-FIT, there is potential for patients to experience trauma, specifically emotional trauma in the event of a FIT positive for occult blood and physical trauma with subsequent follow-up procedures (colonoscopy, diagnosis).[56,57] Flu-FIT will follow a trauma informed approach,[58] particularly for patients that may have FIT results positive for occult blood. Patients will be counseled on that fact that a positive FIT indicates the presence of blood in the stool, which can be caused by many factors and is not a diagnosis of cancer. A positive FIT, however, does require follow-up with a colonoscopy, which can diagnose and remove pre-cancerous growths and some early cancerous growths. The patient will be notified that the results have been sent to their primary care provider who will discuss the next steps with them. Additionally, patients from CCH Clinics and BMG Clinics will have access to chaplain services for spiritual support. However, phone numbers for cancer support services, will be provided upon patient request~~at the time that the positive FIT results are reported to the patient~~ to ensure that the patient has adequate support in the interim.

American Cancer Society	http://www.cancer.org/treatment/supportprogramsservices/index 1-800-ACS-2345 or visit www.cancer.org.
Colorectal Cancer Network	www.colorectal-cancer.net
Cancer Care – Free Telephone Support Groups and Education Workshops	1-800-813-HOPE or 212-712-8080

References[59]

Referrals

Patients of CCH clinics and BMG clinics (BMG is tied to the Baptist Memorial Health System) would be automatically referred to their respective primary care providers in the event of a positive FIT result. For patients that are vaccinated in Walgreens Pharmacy, pharmacists will notify the patients' listed primary care providers with the positive FIT results prior to notifying the patient. Uninsured patients without a primary care provider will be referred to CCH (HRSA funded Community Health Center) for a follow-up visit with a physician to determine the next steps in their diagnosis and treatment. Dr. Philip Bowden, a local gastroenterologist, has also agreed to take on uninsured patients requiring a colonoscopy. The nature of Flu-FIT requires constant interprofessional interaction and collaboration between the pharmacies and clinics, reinforcing linkages throughout the process.

Promotion

Flu-FIT promotional materials (**Appendix D**) will be used in each practice participating practice site throughout the entire grant period. During Year 2 of the grant period, the Flu-FIT Committee will collaborate with LocalCares, A.C. Wharton, and Dr. Philip Bowden to develop a media campaign (local news channels, radio, newspaper, websites, and social media) to emphasize the importance of CRCS. This promotional campaign will be a continuation of their 100% by 2020 campaign. Specific goals and objectives for the promotion of Flu-FIT may be found in the work plan. This campaign will be released in September and continue through

January. At the conclusion of Year 2, additional promotion of the annual influenza vaccine will be considered to increase participation in Flu-FIT during Year 3.

See Appendix E for the Logic Model and Appendix F for the Work Plan.

Planning and Piloting (Grant period starting in March)

The first three months (Year 1 March to June) will focus on collaboration between the SCHD, the CAG (additional details in section below), and clinic and pharmacy leaders to gain input on the optimal implementation of Flu-FIT, including staff training processes, workflow, and fidelity monitoring. During this time, clinic/pharmacy leaders will also assist with recruiting patients to participate in focus groups to gain insight on their perceptions on CRCS, the FIT, and barriers preventing CRCS adherence. Flu-FIT Champions, individuals responsible for training clinic/pharmacy leaders and staff and ensuring the fidelity of Flu-FIT, and data entry will also be hired and trained during this time. The standardized training program will be reviewed by clinic and pharmacy leaders and revised as needed. A software programmer will be contracted to obtain information on patients aged 50 to 75 years that had primary care visits from CCH and BMG clinic electronic health records. The Flu-FIT Champions will evaluate this data from the CCH and BMG Clinics to determine the number of patients eligible for CRCS and the number of patients adherent to CRCS recommendations in the previous year to determine a baseline for CRCS rates. This is only possible for the CCH and BMG clinics due to the availability of electronic health records. From July to the end of August (months 5-6), Flu-FIT Champions will train clinic/pharmacy staff on the proper implementation of Flu-FIT, including screening, delivery, CRCS education/counseling, documentation, follow-up, and referral. Clinic/pharmacy leaders will prepare their respective settings for the implementation of Flu-FIT, including

preparing areas for CRCS education/screening, record keeping processes, and setting up systems to communicate with primary care providers readily. Flu-FIT will be ready to pilot by the end of month 6 of the grant period, starting September 1st.

Flu-FIT will be piloted in one BMG Clinic, three Walgreens pharmacies, and two CCH Clinics from September to the end of February of Year 1. During this pilot period, Flu-FIT Champions will visit each site bi-weekly to ensure fidelity to Flu-FIT, proper documentation of Flu-FIT interactions, and to address any improvements that can be made in the implementation of Flu-FIT. The Flu-FIT committee (Program Director, Flu-FIT champions) will meet on a monthly basis to discuss the progress of Flu-FIT in each of the three settings. Updated Flu-FIT data will be given to the biostatistician monthly. Readiness will be determined by the attainment of the following outcomes by the end of March of Year 1:

- 100% of staff in each setting trained to 100% Flu-FIT competency as determined by Flu-FIT Champion
- Telephone follow-up reminder two weeks after Flu-FIT encounter (verbal contact, voicemail not sufficient) with >90% of patients that were given a FIT
- Complete documentation of >90% of patients given a FIT (CRCS status, date FIT offered, date FIT returned, date of patient reminder, date FIT result received by setting, FIT result, date patient notified of FIT, patient's primary care provider)
- Notification of FIT results to patient's primary care provider (verbal confirmation, fax confirmation) for 100% of patients that completed and mailed their FIT

Getting to Outcomes™ will be used to guide Flu-FIT program planning and implementation activities.[60] More detailed goals, objectives, and specific milestones can be found in the Work Plan in the **Appendix F**.

Community Advisory Group Involvement

The first month of the grant period will involve the establishment of a Community Advisory Group (CAG) for Flu-FIT. This group will be comprised of a diverse group of community leaders including educators, healthcare providers, community based organizations, and local churches (**See Appendix A**). The CAG will oversee the quality and extent of the participation of the Shelby County residents in Flu-FIT and recommend program plans and priorities to the program director of Flu-FIT. Additional members may need to be recruited, including businesses and media to achieve a more diverse group.

Community Mobilization

The Shelby County Health Department will implement the following strategies as laid out in the Strategies Guided by Best Practice for Community Mobilization.[61] The SCHD, will serve as strong leadership to drive community-wide efforts for Flu-FIT. The SCHD has been a leader in community mobilization efforts in the past and will provide both the infrastructure and human resources for Flu-FIT. The SCHD will establish a formal structure for Flu-FIT, engaging community partners in the planning, implementation, and evaluation of the program. Diverse non-profit organizations, institutions, community leaders, employers, and residents (**See Appendix A**) will be engaged in the Community Advisory Group (CAG). There will be a constant flow of information to the CAG; the CAG will meet on a semi-annual basis and receive updates on program progress on a quarterly basis via email.

Continuous Quality Improvement

After the pilot period, the Flu-FIT champions will continue bi-weekly visits to each site to ensure fidelity to Flu-FIT, proper documentation of Flu-FIT interactions, and to address any improvements that can be made in the implementation of Flu-FIT. The Flu-FIT committee (Program Director, Program Coordinator, Flu-FIT champions) will meet on a monthly basis to discuss the progress of Flu-FIT in each of the three settings with weekly conference calls. Processes will be revised as needed with approval from the program director and documented. Processes should not be changed without approval from the program director.

Communication

We recognize that communication will be essential to the success of Flu-FIT and Shelby County. The Project Director, Project Coordinator, and Flu-FIT Champions (more detailed descriptions in Project Management) will meet on a monthly basis in person to discuss the progress of the program. In addition, they will also have weekly conference calls to touch base. The Flu-FIT Champions will meet with their respective clinic/pharmacy staff on a bi-weekly basis during their site visits. The Project Director will meet with the CAG on a semi-annual basis and send updates to the CAG quarterly. The Project Director will meet with clinic/pharmacy leadership on a quarterly basis. During the entirety of the grant period, clinic/pharmacy leaders and staff will be able to meet with the Program Coordinator or Program Director as needed to address issues beyond a Flu-FIT Champion's knowledge/scope.

Plans for Sustainability

The SCHD plans for Flu-FIT to be sustainable after the three year grant period. The main financial cost of this program is for SCHD Flu-FIT staff and FIT tests. Most insurance companies will cover FITs obtained through a primary care provider. Through collaboration with the ACS, funding can be acquired for FIT tests for patients that have to pay out of pocket for

FITs obtained through a pharmacy. Additionally, we can involve Fred's Pharmacy, which gave out FITs free of charge in 2015.[62] The costs of chemotherapy treatment for colorectal cancer increases with later stages ($11,624 local stage to $15,576 distant stage in 1992 dollars), while the cost of screening with the FIT is around $7.50 and the cost of follow-up colonoscopy with biopsy ranges between $1,640 and $4,920 in Shelby County.[76, 77] The primary goal for sustainability is to integrate Flu-FIT as a common healthcare practice. The results and lessons learned from this project will be shared at various meetings and conferences to reach public health professionals and other health care providers. We are considering presenting these results at the CDC Cancer Survivorship Conference, American Public Health Association Conference, and/or the American Association for Cancer Education Conference. Fellow health care providers have shown interest in presenting the results to the Memphis Physicians Association, Tennessee Nurses Association (TNA), and the Tennessee Pharmacists Association (TPhA). We are confident that the processes are sustainable in the setting of CCH clinics and BMG walk-in clinics, given staff will follow existing processes in each practice setting, requiring minimal extra work. For Walgreens Pharmacy, sustaining Flu-FIT may be more challenging because extra follow-up is required. Through the pilot/planning period, we will work with the pharmacy staff to revise work flow processes, which may involve reverting to the original Flu-FIT program approach involving Flu-FIT Champions following up with primary care providers and patients to relieve the workload from pharmacists. However, we expect that pharmacy interns will provide adequate assistance since interns are typically regarded as an addition to existing staff. Health care providers' satisfaction with Flu-FIT will be evaluated using an annual survey. Results will be used to improve the following year's workflow processes.

Challenges

We expect that the majority of the challenges will come from implementing Flu-FIT in Walgreens Pharmacy with major adaptations. We will need to be vigilant in obtaining feedback from pharmacists and interns and revising workflow processes. An alternative plan, involving Flu-FIT Champions delivering the CRC education portion of Flu-FIT during designated Flu-FIT vents, is in place if the proposed approach is deemed unsustainable. Across all the settings the major challenges involve 1) ensuring that the patients actually use and mail the FIT to the laboratory or clinic and 2) ensuring that patients and primary care providers are notified in a timely fashion. We will address any challenges that arise during the pilot period and through bi-weekly site visits from the Flu-FIT Champions. We expect optimized workflow processes by the end of the pilot period. Additionally, we will need to ensure that patients actually follow-up with their primary care providers in the event of a positive FIT result. We may need to employ more Flu-FIT Champions to assist with patients reminders and follow-up to relieve the workload from pharmacy and clinic staff. Currently, the planned approach involves Flu-FIT delivery during routine patient visits, rather than designated Flu-FIT events to maximize the number of patients reached. If the planned approach is not well received by the clinic/pharmacy staff, we will discuss the option of switching to the use of designated Flu-FIT events. This switch will also be an option if there were difficulties with fidelity monitoring (i.e. very few Flu-FIT eligible patients encountered during bi-weekly site visits).

Performance Measures and Evaluation

The data for the following performance measures will be compiled on a quarterly basis and reported to the funder on a semi-annual basis:

Table 6: Performance Measures

Performance measures	**Data sources**	**Person(s) responsible**
Baseline: Number of patients aged 50 to 75 with clinic visits from September 2016 to February 2016	EMR	Software programmer
Baseline: Number of patients aged 50 to 75 with clinic visits from September 2016 to February 2016 that are up to date with CRCS by March 1st, 2016 (or date requested)	EMR	Software programmer
Implementation period: Number of patients aged 50-75 that had clinic visits from September 2017 to February 2017	EMR	Software programmer
Implementation period: Number of patients aged 50-75 that had clinic visits from September 2017 to February 2017 that are up to date by March 1st, 2017 (or date requested)	EMR	Software programmer
Number of patients aged 50-75 that received influenza vaccine during Flu-FIT implementation (September through February)	Flu-FIT log, EMR	Software programmer Clinic/pharmacy staff, Flu-FIT Champions
Number of patients aged 50-75 that received influenza vaccine and FIT (September through February)	Flu-FIT log, EMR	Software programmer Clinic/pharmacy staff, Flu-FIT Champions
Number of FITs returned	Follow-up log	Log documentation: Clinic/pharmacy staff Data collection/data entry: Flu-FIT Champions
Number of patients requiring 2 week reminder	Follow-up log	
Number of patients that received 2 week reminders	Follow up log	
Number of normal FIT results	Follow up log	
Number of abnormal FIT results	Follow-up log, tracking log	
Number of invalid FIT results	Follow-up log	
Number of referrals for abnormal FIT	Tracking log	
Number of patients with abnormal FlT that completed colonoscopy	Tracking log	
Demographics (gender, ethnicity, age, insurance status, setting the patient received FIT)	Flu-FIT log, EMR, pharmacy records	

Clinic/pharmacy staff will use the Flu-FIT Log, Follow-up Log, and Tracking Log (**Appendix G**) to document Flu-FIT encounters during the program period. These logs will also serve as data sources for the performance measures. Flu-FIT Champions will be responsible for reviewing these logs for completeness and fidelity. In addition, Flu-FIT Champions will be responsible for summarizing the data collected from the logs on a bi-weekly basis. Reports will be submitted to the Project Coordinator on a monthly basis. Demographic information for

participating patients will be collected through patient information systems (electronic health records, pharmacy system) using the patient's name and date of birth by the Flu-FIT Champions. Baseline clinic screening rate data and implementation screening rate data for clinic patients will be collected by the software programmer through the clinics' electronic health records. The software programmer will develop these reports on a quarterly basis and submitted to the Project Coordinator. These reports will be used for continuous quality improvement. For instance, if a large percentage of FIT results are invalid, the Flu-FIT Champions will observe staff more frequently and provide additional training on educating patients on how to use the FIT. The Project Director and Flu-FIT Champions will discuss the reports on a monthly basis.

Implementation and Outcome Evaluation

To ensure that this program is implemented as intended and results in the expected outcomes, implementation evaluations and outcome evaluations will be conducted on an ongoing basis throughout the grant period. These evaluations will be conducted by the joint efforts of the Flu-FIT Champions, clinic/pharmacy staff, and the hired software programmer. Analyses will be performed by the biostatistician on a quarterly basis.

Table 7: Implementation Evaluation

Implementation measures	Data Source(s)	Person(s) responsible
Number of participating staff members trained on Flu-FIT	Flu-FIT competency evaluations	Flu-FIT Champions
Flu-FIT competency scores	Flu-FIT competency evaluations	Flu-FIT Champions
Number of Flu-FIT eligible patients vaccinated	Flu-FIT log	Flu-FIT Champions
Number of Flu-FIT eligible patients that accepted FIT	Flu-FIT log	Clinic/pharmacy staff
Number of patients that returned FIT within 2 weeks of Flu-FIT encounter	Follow-up log	Clinic/pharmacy staff
Number of patients that received phone or postcard reminder 2 weeks after Flu-FIT encounter	Follow-up log	Clinic/pharmacy staff
Number of FITs returned to the clinic	Follow-up log	Clinic/pharmacy staff
Number of FITs with valid result (able to be read)	Follow-up log	Clinic/pharmacy staff
Number of FITs with positive result	Follow-up log	Clinic/pharmacy staff
Number of patients with negative FITs notified of result	Follow-up log	Clinic/pharmacy staff
Number of patients with positive FITs that were notified of results	Follow-up log	Clinic/pharmacy staff
Number of patients with positive FIT with colonoscopy scheduled	Tracking log	Clinic staff/ Flu-FIT champions
Number of patients with positive FIT with colonoscopy completed	Tracking log	Clinic staff/Flu-FIT champions
Number of patients without primary care provider that were referred to CCH	Tracking log	Pharmacy staff
Implementation goals		
- All participating staff trained to 100% Flu-FIT competency - <5% of FIT results invalid - 100% of patients notified of FIT results (positive or negative) - 100% of primary care providers notified of FIT results (positive or negative) - Telephone follow-up reminder two weeks after Flu-FIT encounter (verbal contact, voicemail not sufficient) with >90% of patients that were given a FIT - Complete documentation of >90% of patients given a FIT (CRCS status, date FIT offered, date FIT returned, date of patient reminder, date FIT result received by setting, FIT result, date patient notified of FIT, patient's primary care provider) - Notification of FIT results to patient's primary care provider (verbal confirmation, fax confirmation) for 100% of patients that completed and mailed their FIT - Scheduled colonoscopy for 100% of patients with positive FIT - Referral to CCH for patients that received Flu-FIT in the pharmacy and had a positive FIT result		

Table 7 lists the implementation evaluation measures for Flu-FIT across the clinic and pharmacy settings. These measures are intended to ensure that Flu-FIT is being delivered as intended, encounters are documented properly, and staff members have follow-up with patients with reminders and FIT results. Flu-FIT Champions will document the Flu-FIT competency scores for all participating staff and ensure that all staff attains 100% Flu-FIT competency prior to the implementation of the program. Clinic/pharmacy staff will fill in patient information using

the Flu-FIT Log, Follow-up Log, and Tracking Log (**Appendix G)** with every encounter, follow-up, etc. Flu-FIT Champions will be responsible for reviewing these logs, entering the data electronically for analysis, and performing the necessary calculations to obtain the measures desired on a bi-weekly basis. This information will be reported to the Project Coordinator on a monthly basis. The logs will allow for continuous quality improvement, allowing the Flu-FIT Champions determine if there are workflow issues that need to be addressed. For instance, if a Flu-FIT Champion finds that a very low percentage of FITs are being completed and returned and also very few of the patients have been sent a 2 week reminder, the Flu-FIT Champion may discuss with staff the barriers that may be causing this issue. The solution may also involve re-training on sending 2 week reminders. The collection of this data will allow for the Flu-FIT Committee to identify key successes, lessons learned, and challenges, which will be discussed with clinic and pharmacy staff.

Table 8: Outcome Evaluation

Outcome Measures	**Data Source(s)**	**Person(s) responsible**
CRCS knowledge test scores	CRCS knowledge test	Clinic/pharmacy staff (survey administration) Flu-FIT Champions (survey scoring)
Baseline CLINIC: Number of patients aged 50 to 75 with clinic visits from September 2016 to February 2016	EMR	Software programmer
Baseline CLINIC: Number of patients aged 50 to 75 with clinic visits from September 2016 to February 2016 that are up to date with CRCS by March 1st, 2016 (or date requested)	EMR	Software programmer
Implementation period CLINIC: Number of patients aged 50-75 that had clinic visits from September 2017 to February 2017	EMR	Software programmer
Implementation period CLINIC: Number of patients aged 50-75 that had clinic visits from September 2017 to February 2017 that are up to date by March 1st, 2017 (or date requested)	EMR	Software programmer
Number of patients aged 50-75 vaccinated	Flu-FIT log	Clinic/pharmacy staff, Flu-FIT Champions
Number of patients aged 50-75 vaccinated that were up-to-date with CRCS at the time of vaccination	Flu-FIT log	Clinic/pharmacy staff, Flu-FIT Champions
Number of patients aged 50-75 vaccinated that were not up-to-date with CRCS at the time of vaccination	Flu-FIT log	Clinic/pharmacy staff, Flu-FIT Champions
Number of patients given FITs	Flu-FIT log	Clinic/pharmacy staff, Flu-FIT Champions
Number of patients that returned FITs	Tracking log	Clinic/pharmacy staff, Flu-FIT Champions
Number of patients with positive FIT results	Tracking log	Clinic/pharmacy staff, Flu-FIT Champions
Number of patients with positive FITs that were notified of results	Follow-up log	Clinic/pharmacy staff
Number of patients referred to PCP or CCH	Tracking log	Clinic/pharmacy staff, Flu-FIT Champions
Number of patients with positive FIT results that followed up with a colonoscopy	Tracking log	Clinic/pharmacy staff, Flu-FIT Champions
Patient satisfaction	Patient satisfaction survey	Flu-FIT Champions
Staff/health care provider satisfaction	Health care provider satisfaction survey	Flu-FIT Champions
Outcome goals		
>50% improvement in patient knowledge of CRCS from baseline >50% of patients that received the FIT actually used and mailed the FIT >90% of patients mailed the FIT were followed-up with their results and their primary care provider was notified 20% increase in CRCS rates in each clinic practice setting (all patients aged 50-75yo with clinic visits in specified period) 30% increase in CRCS rates in participating patients 30% or higher FIT adherence rate in patients vaccinated Scheduled colonoscopy for 100% of patients with positive FIT Increased patient and health care provider satisfaction with Flu-FIT over the grant period		

Table 8 lists the outcome evaluation measures for Flu-FIT across the clinic and pharmacy settings. The outcome evaluation will ensure that Flu-FIT has accomplished the proposed outcomes. This will involve the use of similar data sources used for both the performance measures and the implementation evaluation.

For the CRCS knowledge evaluation, clinic/pharmacy staff will offer Flu-FIT eligible patients the option of completing the CRCS knowledge survey, using a $5 gift card as incentive. The results gathered from Year 1 will serve as a measure of the community's baseline knowledge. This survey will be offered in subsequent years during Flu-FIT implementation, following the interrupted time series design. We expect to see an increase in knowledge in Flu-FIT participants over the grant period.

In order to obtain the baseline screening rate for clinic sites, the software programmer will be tasked with pulling data for clinic visits between September 1, 2016 and February 28, 2016, during the year prior to the grant period (grant period starts March 1, 2017). From there they will pull the patients that were between 50 and 75 years old that had clinic visits during that time period. From this information we can determine how many of these patients were up-to-date with CRCS (colonoscopy in the past 10 years, or FOBT/FIT in the past year) by March 1, 2017 and determine the baseline screening rate for each practice setting (involved in pilot period or not involved in pilot period). This process will occur again, assessing the patients during the implementation period in all settings during Year 1. The baseline screening rates and implementation period screening rates in the settings involved during Year 1 will be compared to the screening rates in the settings not involved during Year 1 following the non-equivalent group pre-test, post-test design. We expect screening rates to be increased. EMR data will be collected and reported by the software programmer on a quarterly basis.

In order to obtain the baseline screening rate for pharmacy sites, since there is no EMR to determine screening history, we will need to rely on patients' self-report. During Year 1, patients receiving the influenza vaccine that are aged 50-75 will be asked about their CRCS history by pharmacy staff. These results will serve as the baseline screening rate. In March, the Flu-FIT logs and tracking logs will be assessed to determine the number of patients that completed the FIT to determine the CRCS rate after Flu-FIT implementation, following the within-subjects design.

As stated before, clinic/pharmacy staff will fill in patient information using the Flu-FIT Log, Follow-up Log, and Tracking Log (**Appendix G)** with every encounter, follow-up, etc. Flu-FIT Champions will be responsible for reviewing these logs, entering the data electronically for analysis, and performing the necessary calculations to obtain the measures desired on a bi-weekly basis. This information from the logs will be reported to the Project Coordinator on a monthly basis.

Patient satisfaction surveys (**Appendix I**) will be administered via phone to every patient that accepted a FIT by either the clinic/pharmacy staff or a Flu-FIT Champion between October and March of every year. The pharmacy specific portion of the survey is based on the survey distributed in the pharmacy pilot. Patients that complete the survey will be mailed a $5 Visa gift card. Flu-FIT Champions will score these surveys and perform data entry. These results will be reported annually by May. The results will be used to assess needed changes to the program and discussed with the CAG.

Health care provider satisfaction surveys (**Appendix I**) will be administered on paper, in-person, to the participating health care providers (nurses, medical directors, pharmacists, interns) by the Flu-FIT Champions every year in March. This survey is fairly short, and we expect health

care providers to complete this survey, since this is their pportunity to express their thoughts and opinions regarding the program. -The health provider satisfaction survey is based on the survey used after the San Francisco pilot (**Appendix I**). During this time, Flu-FIT Champions and the Project Coordinator will also interview staff members. The results will be reported annually in May and be used to assess needed changes to the program and discussed with the CAG.

BRFSS Survey

We propose that the following survey questions will be added to the BRFSS survey regarding CRCS:

17.1a How often do you think you need to use blood stool test (at home kit)?
- 1→Once a year
- 2→Once every 5 years
- 3→Once every 10 years
- 7→Don't know/not sure
- 9→Refused

*CRCS knowledge

17.1b If you used a home kit, did a healthcare provider contact you to remind you to mail the test?
- 1→Yes
- 2→No
- 7→Don't know/not sure
- 9→Refused
- *Determine how often health care providers remind patients to return home tests

17.6 When was the last time a healthcare provider (physician, nurse, physician's assistant, pharmacist) recommended that you get a screened for colorectal cancer?
- 1 → Within the past year (anytime less than 12 months ago)
- 2 → Within the past 2 years (1 year but less than 2 years ago)
- 3 → Within the past 3 years (2 years but less than 3 years ago)
- 4 → Within the past 5 years (3 years but less than 5 years ago)
- 5 → Within the past 10 years (5 years but less than 10 years ago)
- 6 → 10 or more years ago
- 7 → Don't know / Not sure
- 9 → Refused

17.6a If they recommended you get screened for colorectal cancer, what test did they recommend?
- 1→Colonoscopy
- 2→Flexible sigmoidoscopy
- 3→Home test (FIT or FOBT)
- 7→Don't know/not sure
- 9→Refused

*Determine how often health care providers are recommending CRCS to patients

Existing BRFSS questions[63]

Applicable Laws

We have reviewed the applicable laws, policies, procedures and will provide documentation confirming that we may collect and report data on all required performance

measures from all participants by the end of the planning and piloting period. Most importantly we will ensure protection of personal health information (PHI) through de-identification of patient information. Clinic and pharmacy staff members are already trained in HIPAA. Flu-FIT Champions will ~~and will~~ assign random ~~patient~~ identification numbers to patients for submission ~~submit~~ to the health department. Forms with the identification numbers and corresponding patients will be stored in each practice setting during the grant period. We will also require IRB approval for the handling of this information if the results of this program are used in research publications.

Potential Obstacles

The major obstacle is the collection of data without overburdening clinic and pharmacy staff. Most of the data collection is done in the process of screening the patient and gathering the appropriate information for follow-up. However, the amount of time taken can be a burden to staff members. In the event that data collection processes become overwhelming for clinic/pharmacy staff, Flu-FIT members will be responsible for data collection and patient follow-up.

Capacity of Applicant Organization

Shelby County Health Department (SCHD)

The mission of the Shelby County Health Department is to "promote, protect, and improve the health and environment of all Shelby County residents." The Division of Health Services serves the City of Memphis and the Shelby County government to promote public health practices that safeguard and improve the quality of life for approximately 900,000 residents of Shelby County. The Department's responsibilities include closing the gaps in health

status and access to care among the community's diverse populations, fostering current and building additional partnerships with local health agencies, public and private agencies, community-based coalitions, providers, consumers, educational / academic institutions, and other interested groups, improving the quality and cultural sensitivity of the health-related operations, services, and programs, and reducing the occurrence of preventable disease and premature death among all Shelby County residents.[32] The SCHD has and enforces a policy following Title VI of the 1964 Civil Rights Act, which states that "no person in the United States shall, on the grounds of race, color or national origin, be excluded from participation in, be denied the benefit of, or be subjected to discrimination under any program or activity receiving federal financial assistance." [64] The Shelby County Health Department continues to fulfill its mission and responsibilities with the implementation of Flu-FIT.

Zoey Madlock serves as the director of the health department/ Health Services Division and oversees five departments: Administration and Finance, Environmental Health Services, Community Health Services, Health Planning and Promotion, and Public Health Safety. The organizational chart may be found in **Appendix J**. Flu-FIT will be implemented through a joint effort between Community Health Services and Health Planning and Promotion, which are operated by Matthew Holman and Cara Nunnally, respectively.[65] Employee performance is formally evaluated semi-annually. Informal evaluations are performed quarterly. As a government entity, the health department has seen minimal turnover.

Health Planning and Promotion:

The department of Health Planning and Promotion performs county-wide health assessments, assures access to preventative and primary health care, and promotes good health through several initiatives and programs.[67] This department has experience in promoting and

educating Shelby County residents on chronic disease prevention, focusing particularly on tobacco use, through the Freedom from Smoking program. Freedom from Smoking is an evidence-based smoking cessation program that involves a systematic approach to quitting smoking that focuses on behavior change in adults.[68] During fiscal year 2015, the bureau educated 4,000 residents, a 60% increase from the previous year. For fiscal year 2016, Shelby County is expected to receive close to $500,000 in tobacco settlement funds for Freedom from Smoking to serve an additional 6,000 residents.[65]

Community Health Services:

The department of Community Health Services is the largest department in the Health Services Division. This department provides ambulatory, primary, and preventative health care services to a large population through a network of eight clinics.[65] These clinics offer services including dental services, immunizations, family planning, nutrition programs, prenatal counseling, and school health programs. Programs offered in the community teach citizens how to be well and stay well.[69] During fiscal year 2015, 64,500 vaccinations were administered. In addition to operating eight clinics, this department continues to implement and evaluate two evidence-based home visit programs, the Healthy Start Initiative and Help Us Grow Successfully (HUGS) to improve maternal health and birth outcomes, especially for teen mothers and high-risk women. For fiscal year 2015, 75% of enrolled prenatal and infant families, about 415 families, received services provided by these two programs. While this department focuses mainly on child and maternal health, Community Health Services has valuable experience in the implementation and evaluation of evidence-based programs. Every year, this department manages a budget of exceeding $1,000,000.[65]

A summary of the experience of the SCHD can be found in **Appendix K.**

Partnerships

The SCHD has many existing partnerships in the community and is very experienced in collaborating with local organizations and institutions. During 2011, the SCHD produced a Community Health Improvement Plan, in partnership with a diverse group of 32 local organizations (**Appendix L)**, including Baptist Memorial Health Care.[37] The development of this health improvement plan involved use of results compiled from existing national, state, and local data sources. This assessment also required gathering new data through surveys on community strengths and metrics (quality of life, health outcomes, etc) and group discussions. These results were used to determine the best course of action to improve community health. In addition, Zoey Madlock serves as a member of the leadership team for Healthy Shelby, which includes representatives from both Baptist Memorial Health Care and Christ Community Health. Healthy Shelby is a collective-impact driven initiative that was launched in 2011 that is focused on better health, better care, and lower costs as strategies for economic vitality.[70] Partnerships will be discussed in more detail in the **Partnerships and Collaboration** section.

Partnerships and Collaboration

Since Flu-FIT will be adapted to a community that is culturally and ethnically different from the San Francisco community served in the pilot study, the involvement of diverse partners will be integral for the successful implementation of Flu-FIT in Shelby County. The partners with the most involvement are Christ Community Health clinics, BMG Walk-in Clinics, and Walgreens, since Flu-FIT will be directly implemented in these settings.

Christ Community Health Center

Christ Community Health Center (CCHC), established in 1995, is one of the largest Christian health centers in the nation and the largest primary healthcare provider in Shelby County. The mission of Christ Community Health is to "provide high quality healthcare to the underserved in the context of distinctively Christian service." Each clinic is strategically located in Memphis communities that are deficient in resources and services.[31] To date, CCHC serves over 60,364 patients annually, providing a wide array of health services, including preventative care, through its clinics.[71] The patients served by CCHC range from neonates to adults over 65 years of age. CCHC has also implemented a mobile health care clinic in partnership with Baptist Memorial Health called Operation Outreach.[72] Operation Outreach offers complete acute and primary care, disease prevention, and guidance to Memphis' homeless population, serving over 1,000 of the homeless in the Memphis area each year. Christ Community Health is also a participant of the Healthy Shelby Initiative. As a HRSA-funded health center, Christ Community Health frequently collects performance measures data for annual reports and to guide continuous improvement of the health services offered.

As stated in the Program Approach section, CCHC will be responsible for implementation of Flu-FIT in five of its clinics. Trained nursing staff will be responsible for the actual implementation of Flu-FIT, including determining patients' eligibility for the FIT, using written and video instructions to explain the process to the patients, providing patients with the FIT and stamped envelopes for returning the FIT kits to QuestLabs, and documenting the encounter in the Flu-FIT log sheet. Nursing staff will also be responsible for reporting FIT results to the patients and patients' primary care providers and documenting the follow-up. The designated clinic leader and nursing staff will meet on a bi-weekly basis with the Flu-FIT Champion to discuss issues with implementation. The medical director will also be responsible

for providing standing orders for the FIT and contributing to semi-annual Community Advisory Group meetings.

Walgreens Pharmacy

Walgreens is the largest retail pharmacy chain in the US, founded in 1901. The mission of Walgreens is to "help people get, stay, and live well." Walgreens has an extensive history of participating in various preventative health activities. More recently, Walgreens has implemented The Walgreens Way to Well Health Tour, which involves delivering free preventative health tests, education and consultations to adults 18 and over. Over 1,000,000 people have received these free health services through this program since 2005.[73] Walgreens has also worked with local health departments to deliver free HIV screenings. In addition, Walgreens locations in Memphis have an existing partnership with Baptist Medical Group.[74] This collaboration involves direct communication between Baptist Medical Group physicians and Walgreens Healthcare Clinics nurse practitioners to facilitate care coordination, sharing of patient information and enhanced awareness of Baptist Medical Group services.

The pharmacists at Walgreens will be responsible for the actual implementation of Flu-FIT, including determining patients' eligibility for the FIT, using written and video instructions to explain the process to the patients, providing patients with the FIT and stamped envelopes for returning the FIT kits to the lab, and documenting the encounter in the Flu-FIT log sheet. The pharmacists at Walgreens will also be responsible for reporting results to patients and their primary care providers. FIT results will be kept on record for program evaluation. Alternatively, the pharmacist may delegate these responsibilities to a fourth year pharmacy intern, after the intern has been trained by a Flu-FIT champion. Pharmacists have extensive experience in record

keeping and documenting patient care. These responsibilities are similar to those necessary for a pharmacist to complete for the administration of vaccines and for the provision of Medication Therapy Management services.

BMG Walk-in Clinics

Baptist Medical Group (BMG) is a wholly-owned subsidiary of Baptist Memorial Health Care and the Mid-South's largest integrated not-for-profit multispecialty physician practice. Baptist Memorial Health Care is actively involved in improving the health of Shelby County, with existing partnerships with the Shelby County Health Department (Community Health Assessment and Healthy Shelby), Christ Community Health (Operation Outreach), and Walgreens (Baptist Online 2014).[10,72,74] BMG Walk-In Clinics were established to increase patients' access to primary care. The mission of BMG is "to spend more time on patients and less time on the details of managing a practice." BMG follows the three-fold ministry of Christ—Healing, Preaching and Teaching—by providing quality health care. BMG provides a comprehensive range of care for all ages.[75] As a primary care center, BMG has extensive experience in collecting data to continuously improve health services.

BMG Walk-in clinics will have the same responsibilities as those detailed for Christ Community Health. The only difference is that the patient's FIT results will be documented in the Baptist Memorial Health Care System.

Community Advisory Group

In addition to Christ Community Health, BMG Walk-in Clinics, and Walgreens, Flu-FIT will also involve a diverse group of community leaders including educators, healthcare providers, community based organizations, and local churches in the Community Advisory

Group (CAG). The members of the CAG are listed in **Appendix A.** These partners will provide perspective on the planning, implementation, and evaluation of Flu-FIT and the impact of the program on the community. The CAG will meet on a quarterly basis. The CAG will also be updated on program progress via email every month. The partners listed in **Appendix A** have shown support of Flu-FIT for Shelby County and expect the programs to be welcomed by the community. The letters of support may be found in the **Appendix Z.**

Project Management

The organizational chart for this project may be found in **Appendix M.**

Project Director

Cara Nunnally will serve as the Project Director of Flu-FIT. As Project Director, she will be fully responsible and accountable for all aspects of the project throughout the duration of the 3-year grant period and will provide management for all faculty/staff and activities involved in the planning, implementation, and evaluation of the proposed Flu-FIT program. She will oversee six Flu-FIT Champions in the implementation and delivery of Flu-FIT in 5 Christ Community Health clinics, 6 Walgreens pharmacies, and 3 BMG Walk-in Clinics as well as a biostatistician and software programmer. Ms. Nunnally will also be responsible for coordinating monthly meetings with the Flu-FIT committee (Project Director, Project Coordinator, Flu-FIT Champions), the Community Advisory Group, and the representatives from Christ Community Health, Walgreens, and BMG Walk-in Clinics. The health department director Ms. Madlock and the community health services director will serve Ms. Nunnally in an advisory capacity. In addition to her role as Program Director, Ms. Nunnally will serve as back-up when one of the Flu-FIT Champions is unable to conduct an education session or site visit. She has experience with working multiple organizations including professional organizations and community leaders

to coordinate grant activities and will serve as the liaison between project personnel and community partners.

Project Coordinator

A Project Coordinator (to be appointed/hired) will be responsible for the day to day management of all resources assigned to the project and will ensure the goals and objectives laid out in the work plan are met, including ensuring all data collection, reports for the project, and abstracts are completed in a timely manner and maintaining the integrity of the program. The Project Coordinator and Ms.Nunnally will meet monthly with the Flu-FIT Champions, semi-annually with the Community Advisory Group, and quarterly with representatives from Christ Community Health, Walgreens, and BMG Walk-in Clinics to discuss and monitor implementation progress. Whenever an issue arises, they will work with the partners to identify and implement a solution. In order to protect the anonymity of participants, the staff will assign each participant a unique identifier. The identifier will be used in the database to record participation, survey data, baselines, and to track progress.

The Project Coordinator will prepare reports for the Director, partners, and CAG, using data gathered annually from reported Vital Statistics, TN Department of Public Health, and other reputable sources of data as well as data gathered continuously from program participants and community focus groups. Performance measure data will be collected from all participants using a questionnaire at the time of offering Flu-FIT as well as various tracking logs. Patient medical records will be used for participants served in the clinic setting. Partner staff (nurses, pharmacists, pharmacy interns) will give the pre-survey to all participants. Flu-FIT Champions will enter results into a database to track participant demographics and contact patients one year

later for the post-survey. Program evaluation will be conducted using responses from the pre and post surveys. All survey responses will be entered into the program database so that responses can be analyzed collectively.

Additional Key Personnel

Additional key personnel include Flu-FIT Champions and pharmacy and clinic staff. Due to the complexity of the overall program and the variety of practice settings, six Flu-FIT Champions will be hired to oversee the 14 practice sites. Each Flu-FIT Champion will be assigned to oversee 2-3 practice sites each. They will be responsible for carrying out the day-to-day activities laid out in the work plan, namely training, fidelity monitoring, and data collection. Each Flu-FIT Champion will receive an updated job description detailing their roles and responsibilities and an implementation checklist. They will send Ms. Nunnally survey responses and an updated implementation checklist monthly. Flu-FIT Champion will serve as a member of the Flu-FIT committee, which meets monthly to discuss the progress of the program and address any issues. Clinic and pharmacy staff will be responsible for the delivery of Flu-FIT to eligible patients, follow-up on FIT results, and documentation. They will be led by Flu-FIT Champions and their respective medical directors and pharmacists-in-charge. Clinic and pharmacy staff will present Flu-FIT documents to the Flu-FIT Champion on a bi-weekly basis.

As discussed in the work plan, the Shelby County Health Department will ensure that all project staff will be well trained to successfully fulfill their roles and responsibilities. In addition to providing curriculum training, the SCHD will provide at least one day of professional development training per year. The training plan includes professional development topics not limited to: using trauma-informed approach, recognizing and reporting harassment, LGBTQ

inclusion, etc. The SCHD will also work with the CAG to identify ways to strategically build capacity within the Shelby County community. The SCHD works hard to ensure its employees work in a supportive environment with professional development and team building opportunities. Each year, the SCHD conducts an annual Employee Satisfaction Survey. These survey results will continue to be monitored and issues will be addressed as they arise to minimize the amount of staff turnover over the course of the grant. The professional development and retention of clinic/pharmacy staff will be deferred to their respective employers at Christ Community Health, Walgreens, and BMG.

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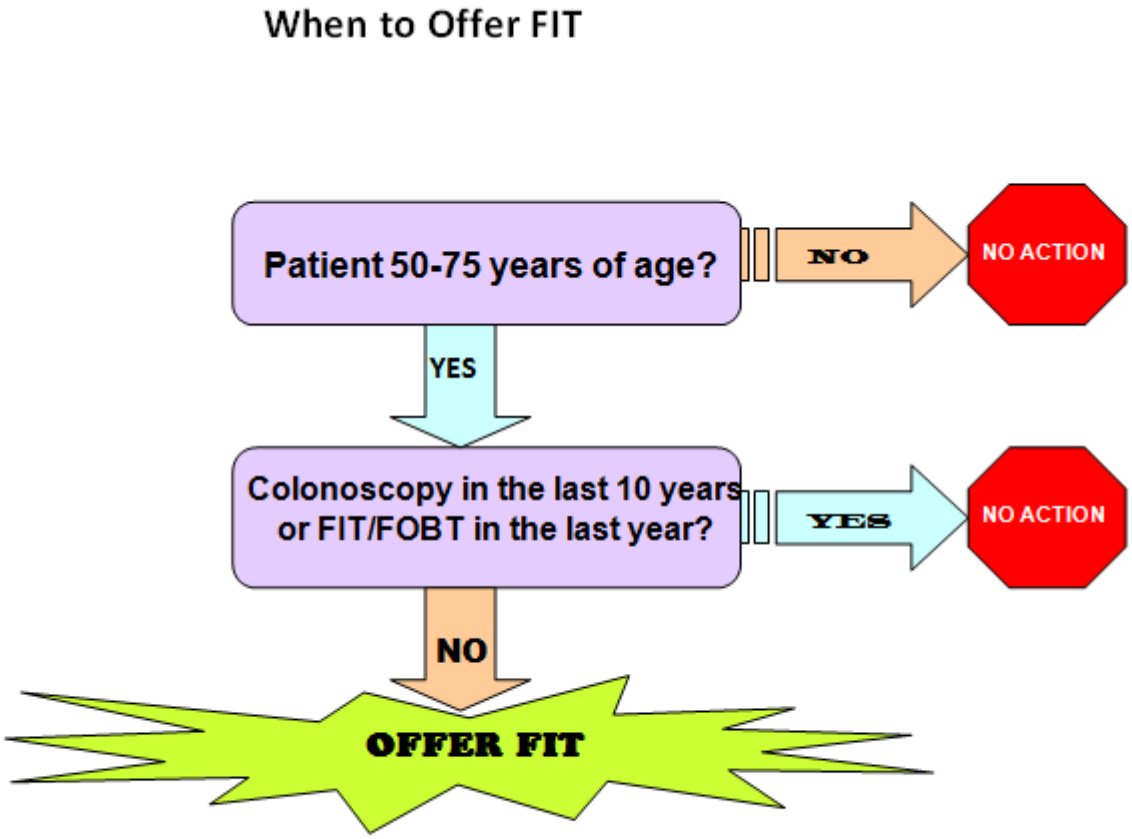
Appendix A. Community Advisory Group for Flu-FIT

Advisory Group Member	Organization description	Contribution
Representative from the American Cancer Society	Non-profit organization	Future funder
Pastor of Bellevue Frayser Baptist Church	Largest and fastest growing African-American Southern Baptist Church in Tennessee	Input on community beliefs and perceived barriers; familiarity with target community
Board member of the American Cancer Society of the Mid-South	Partner with TN cancer coalition	Input on optimizing health promotion /education activities; potential financial support
Team member from FedEx	Major employer in Shelby County	Perspective from major employer in the area; input on expected support from upper management; perspective from working adult over 50
Livestrong program director from the YMCA of Memphis	YMCA- nonprofit organization focused on the health and well-being of the community Livestrong Program- twelve-week, small group program designed for adult cancer survivors.	Perspective on community needs and barriers; provide knowledge of community and perspective of working adult
Virginia Bailey	Daughter of cancer survivor Barbara Ardis. Stepfather passed away from colorectal cancer; administrative assistant from St. Jude Children's Hospital	Perspective from experience of watching one parent survive cancer and one parent pass away from cancer; perspective from hospital administration standpoint;
Former Mayor AC Wharton	Mayor of Memphis from 2009-2015 Active promoter of CRCS	Provide perspective and experience in addressing the needs of Shelby County community; contribute to program promotion
Memphis regional director of TN Cancer Coalition	Coalition dedicated to reduce the burden of cancer that results in risk reduction, early detection, better treatment, and enhanced survivorship	Provide input on the cancer prevention goals for TN and knowledge of past programs and successes
Representative of the Cancer Support Community	Partner of TN Cancer coalition	Provide input on patient support after receiving positive diagnoses
Dr. Philip Bowden of the Mid-South Gastroenterology Group	Memphis area's most comprehensive provider of total digestive wellness, active promoter of CRCS	Provide input from patient care experiences, suggestions for optimizing transitions of care; contribute to program promotion
Health education professor from the University of Memphis College of Public Health	Educator	Provide input on improving patient education
Associate Dean of University of Tennessee College of Pharmacy	Educator	Provide input on capabilities of pharmacy interns and pharmacists Support for use of pharmacy interns

***Medical directors and nurses from Christ Community Health and BMG Walk-in Clinics, as well as pharmacists and pharmacy interns from Walgreens will also contribute to the CAG

Appendix B. Flu-FIT Screening Tool



Appendix C: Flu-FIT Education and Instruction Samples

Colorectal Cancer and FIT/FOBT: Facts and Talking Points for Staff to Use with Patients

Facts about colorectal cancer and screening:

- 2nd leading cause of cancer death in the United States
- More than 50,000 Americans die of colorectal cancer each year
- Colorectal cancer is often preventable with screening
- Early detection and treatment saves lives
- There are more than 1 million colorectal cancer survivors in the United States
- Colorectal cancer screening is recommended between the ages of 50 and 75

Facts about FOBT and FIT kits

- They work by detecting small tiny amounts of blood that can come from colon polyps or early stage colorectal cancer
- If done every year, they can help find polyps and cancers before they become life threatening.
- Studies have shown that high quality FOBT and FIT kits, if done correctly and followed up well, can be similarly effective to colonoscopy for most people.
- They are done at home and mailed into the lab.
- If the FOBT or FIT results are abnormal, you need to get a colonoscopy.
- If you choose to get FOBT or FIT, you need to do it every year, just like a flu shot

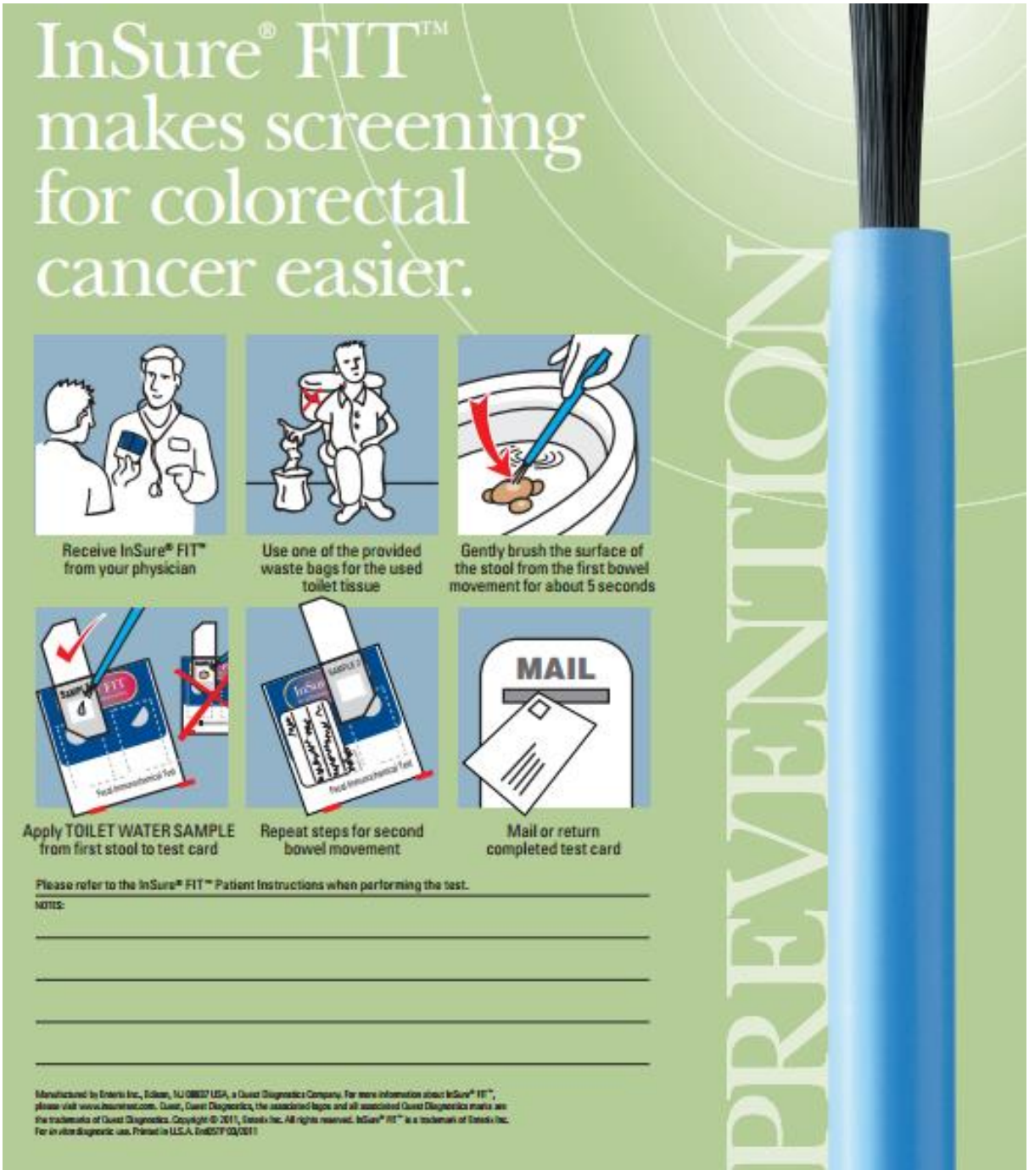
Useful Talking Points for Use with Patients

- We have something extra to offer you today!
- It looks like you are due for a home colon test
- Colon cancer screening can save lives
- Just like a flu shot, all our doctors and nurses recommend home colon tests
- It's very easy -- you can do it in the privacy of your home and mail it in
- We'll make sure the results get to your doctor

Reminders After Giving the Kit To Patients

- Put the kit in the bathroom so it will be there when you need to use it
- Try to complete the kit in the next week if possible
- Write the collection dates on each completed kit
- Mail the kit in as soon as possible after you finish collecting the stool
- Call us if you have a problem with the kit
- Talk to your doctor if you have any other questions about FOBT or FIT

Insure FIT Patient Instructions (given to patient)



Appendix D: Flu-FIT promotional flyer sample

Flu is Preventable!
Colon Cancer is Preventable!

- Just like the FLU,
  COLON CANCER is PREVENTABLE and also TREATABLE and BEATABLE when found EARLY!

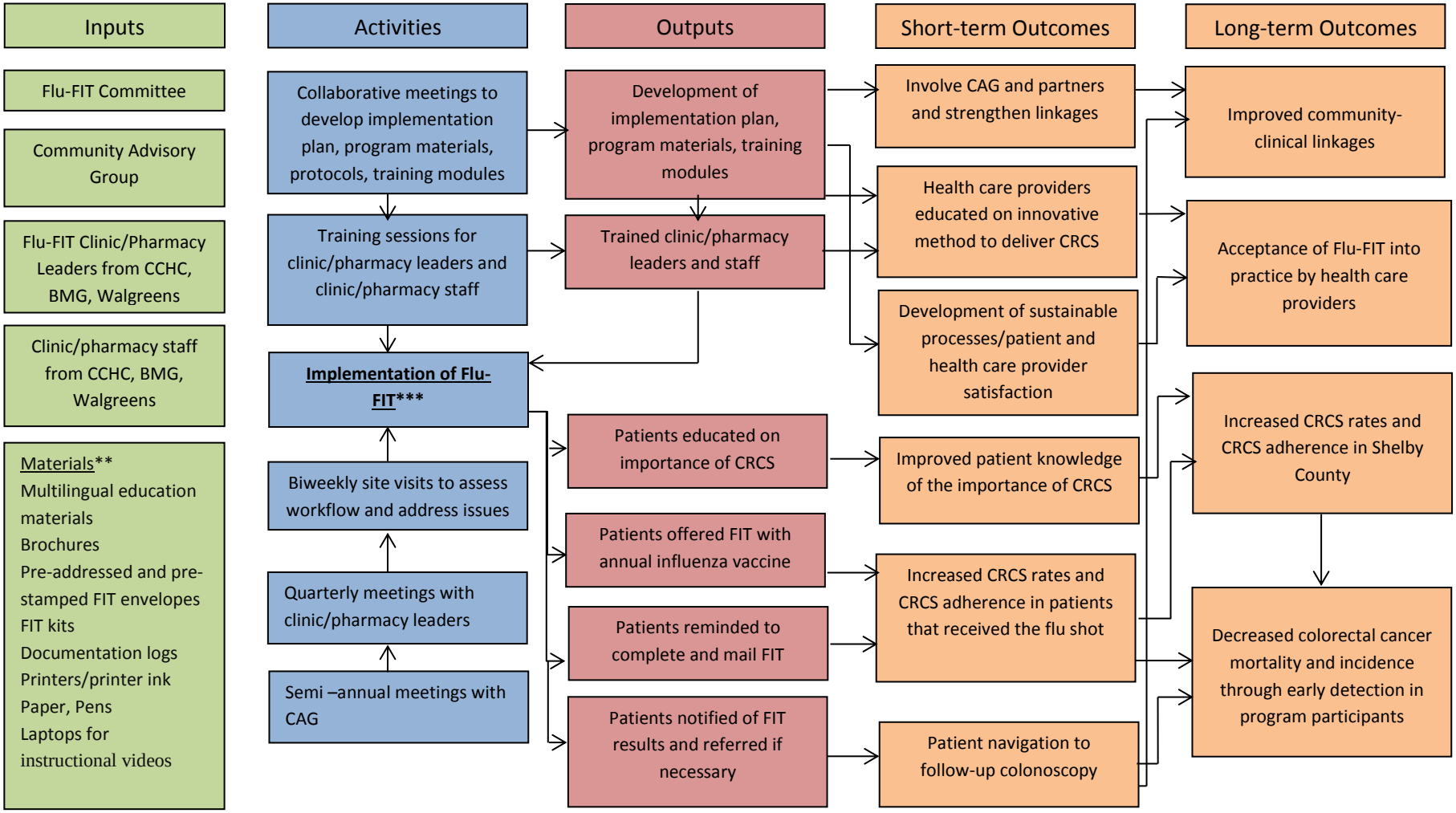
- Colon screening is recommended for healthy men and women aged 50 to 75.

- HOME STOOL TESTS ARE EASY TO DO!
- HOME STOOL TESTS COULD SAVE YOUR LIFE!

- If you are due for colon screening today and have a regular doctor,
  WE WOULD LIKE TO OFFER YOU A FREE HOME COLON TEST!

Appendix E: Logic Model

Impact: Decrease colorectal cancer mortality rates through early detection in the community



*Community Advisory Board members listed in **Appendix A**
**Materials listed are those that are specifically needed for Flu-FIT in addition to materials normally existing in the clinic/pharmacy setting (influenza vaccine, existing systems)

Appendix F: Work Plan for Flu-FIT in Shelby County

Name: Shelby County Health Department (SCHD)
Funds Requested: $**$3,750,148** for grant period (Fiscal year March 2017 to March 2018, grant period March 2017 to March 2020)
Goal : The goal of Flu-FIT is to increase colorectal cancer screening rates and decrease colorectal cancer mortality through early detection in Shelby County by offering a home FIT to eligible patients during annual influenza vaccine activities.

Planning

Objective 1: Complete all hiring, training, and planning activities by September of Year 1 (2017)

Objective 1a: Hire all Flu-FIT staff (Project Coordinator, Flu-FIT Champions), recruit CAG and clinic/pharmacy leaders by May 2017.		
Rationale for Objective 1: In order to optimally deliver the Flu-FIT program to the Shelby County community, additional staff must be hired to assist with day to day activities, health care provider training, data collection, and evaluation.		
Measures of Accomplishments for Objective 1: Hiring of Project Coordinator and six Flu-FIT Champions, recruitment of proposed CAG members and clinic/pharmacy leaders.		
Activities for Objective 1a	**Person(s) responsible**	**Timeline**
1a.1 Hiring of Flu-FIT staff members	Project Director, Human Resources staff	**March 2017-April 2017**
1a.2 Recruitment of CAG members	The Project Director will work with the health department director to contact the proposed members of the CAG with a tentative meeting date	**March 2017-May 2017**
1a.3 Finalization of implementation partners and clinic/pharmacy leaders	The Project Director will contact all implementation partners to determine the clinic/pharmacy leaders and a tentative meeting date	**March 2017-May 2017**

Objective 1b: Develop the implementation plan and finalize adapted Flu-FIT training modules, patient educational materials and surveys by July 2017		
Rationale for Objective 1b: Since the San Francisco differs demographically to Shelby County, the program materials must be adapted to the local population with input from the CAG and implementation partners		
Measures of Accomplishments for Objective 1b: Completion of CAG meeting, Completion of implementation partner meeting, meeting attendance, focus groups completed, finalization of program materials		
Activities for Objective 1b	**Person(s) responsible**	**Timeline**
1b.1 Recruitment of focus group members	The Project Director will recruit 16 focus group members with the assistance of the implementation partners.	**May 2017 to April 2017**
1b.2 Meeting with the CAG to discuss community needs, Flu-FIT training module, program materials, and surveys	Project Director, CAG	**Complete by June 2017**
1b.3 Meeting with implementation partners to discuss the implementation plan, Flu-FIT training module, program materials, and surveys	Project Director, implementation partners	**Complete by June 2017**
1b.4 Finalization of staff training materials	Project Director	**Complete by July 2017**
1b.4 Focus group meetings to gain insight on barriers to CRCS and to test program materials	The Project Director will be responsible for meeting with two focus groups (8 members each). Each focus group will meet up to three times	**Complete by July 2017**
1b.5 Finalization of program materials	The Project Director will email the finalized program materials to the CAG and implementation partners allowing for any adjustments.	**Complete by August 2017**

Objective 1c: Train involved health department staff and participating health care providers to achieve 100% Flu-FIT competency by September 2017		
Rationale for Objective 1c: In order to implement Flu-FIT successfully, all staff members must be well versed in the delivery and evaluation of Flu-FIT		
Measures of Accomplishments for Objective 1c: Completion of training sessions, Flu-FIT competency scores		
Activities for Objective 1c	**Person(s) responsible**	**Timeline**
1c.1 Training sessions for Project Coordinator and Flu-FIT Champions	The Project Director will use the training module during two 2 hour sessions and evaluate each staff member's Flu-FIT competency	**Completed by August 2017**
1c.2 Training sessions for participating health care providers	Flu-FIT Champions will be responsible for providing training sessions to the health care providers at their respective sites and evaluate participants' Flu-FIT competency	**Completed by September 2017**

Piloting

Objective 2: To implement Flu-FIT in six practice sites successfully during Year 1 (2017)

Objective 2a: Train staff on implementation plans by September 2017		
Rationale for Objective 2a: To ensure that Flu-FIT runs smoothly, the implementation plans and work flow processes must be reviewed with participating health care providers		
Measures of Accomplishments for Objective 2a: Dissemination of implementation plans, Training sessions, Completion of clinic/pharmacy walk-through		
Activities for Objective 2a	**Person(s) responsible**	**Timeline**
2a.1 Dissemination of implementation plans/workflow processes to implementation partners	Project Coordinator	**Completed by August 2017**
2a.2 Training sessions on work flow processes for participating health care providers	Flu-FIT Champions	**Completed by September 2017**
2a.3 Pharmacy/clinic walk through two weeks prior to start of Flu-FIT implementation	Flu-FIT Champions	**Completed by mid-September 2017**

Objective 2b: Complete documentation in for >90% of patients aged 50-75 years that received the FIT by March 2017		
Rationale for Objective 2b: Documentation is an integral component of Flu-FIT. Complete documentation increases the likelihood that patients will be followed-up on in a timely fashion.		
Measures of Accomplishments for Objective 2b: Complete documentation in Flu-FIT log, Follow-up log, and Tracking log		
Activities for Objective 2b	**Person(s) responsible**	**Timeline**
2b.1 Documentation of all Flu-FIT encounters in appropriate logs	Clinic/pharmacy staff	**September 2017-March 2017** Ongoing activity
2b.1 Monitoring of all tracking logs to ensure complete documentation	Flu-FIT Champions will be responsible for reviewing these logs for completeness and notifying the appropriate persons to correct any errors during bi-weekly site visits	**September 2017-March 2017** Ongoing, bi-weekly
2b.3 Review of logs with Project Director and Project Coordinator to determine needed changes in workflow processes	Flu-FIT Champions	Ongoing, monthly

Objective 2c: Notification of FIT results to patient's primary care provider (verbal confirmation, fax confirmation) for 100% of patients that completed and mailed their FIT by March 2017		
Rationale for Objective 2c: Flu-FIT relies on referrals to give patients access to further testing if needed. Notifying primary care providers of negative results fosters clinical linkages and good transitions of care		
Measures of Accomplishments for Objective 2c: Notifications documented in Follow-up log		
Activities for Objective 2c	**Person(s) responsible**	**Timeline**
2c.1 Notification of primary care providers.	Clinic/pharmacy staff, Flu-FIT Champions may complete this task if staff need assistance	**September 2017-March 2017** Ongoing activity
2c.2 Documentation of primary care notification	Clinic/pharmacy staff	**September 2017-March 2017** Ongoing
2c.3 Monitoring of all tracking logs to ensure complete documentation	Flu-FIT Champions will be responsible for reviewing these logs for completeness and notifying the appropriate persons to correct any errors during bi-weekly site visits	**September 2017-March 2017** Ongoing, bi-weekly
2c.4 Review of logs with Project Director and Project Coordinator to determine needed changes in workflow processes	Flu-FIT Champions	Ongoing, monthly

Objective 2d: Telephone follow-up reminder two weeks after Flu-FIT encounter (verbal contact, voicemail not sufficient) with >90% of patients that were given a FIT		
Rationale for Objective 2d: Studies have found that patients are more likely to complete the FIT if they are reminded. This is a component that must be feasible for staff members in order for Flu-FIT to be successful		
Measures of Accomplishments for Objective 2d: Notifications documented in Follow-up log		
Activities for Objective 2d	**Person(s) responsible**	**Timeline**
2d.1 Reminder phone calls to patients given FIT.	Clinic/pharmacy staff, Flu-FIT Champions may complete this task if staff need assistance	**September 2017-March 2017** Ongoing activity
2d.2 Documentation of reminders	Clinic/pharmacy staff	**September 2017-March 2017** Ongoing
2d.3 Monitoring of all tracking logs to ensure complete documentation	Flu-FIT Champions will be responsible for reviewing these logs for completeness and notifying the appropriate persons to correct any errors during bi-weekly site visits	**September 2017-March 2017** Ongoing, bi-weekly
2d.4 Review of logs with Project Director and Project Coordinator to determine needed changes in workflow processes	Flu-FIT Champions	Ongoing, monthly

Objective 2e: Maintain partnerships and communication with CAG and implementation partners through Year 1 (2017) and optimize workflow processes for Years 2 and 3		
Rationale for Objective 2e: The CAG and implementation partners will provide valuable input to optimize the workflow processes for Years 2 and 3		
Measures of Accomplishments for Objective 2e: Meetings completed, attendance, meeting minutes, emails sent		
Activities for Objective 2e	**Person(s) responsible**	**Timeline**
2e.1 Meet with CAG to discuss progress and possible improvements	Project Director	Ongoing, semi-annual
2e.2 Update CAG on progress via email	Project Coordinator	Ongoing, quarterly
2e.3 Meet with implementation partners to discuss progress and possible improvements	Project Director	Ongoing, quarterly
2e.4 Finalization of workflow processes for Years 2 and 3 and dissemination to CAG and implementation partners	Project Director	**Completed by June 2018**

Implementation

Objective 3: Successfully implement Flu-FIT 14 practice sites and increase CRCS rates in participating sites

Objective 3a: Train staff on implementation plans by September 2018		
Rationale for Objective 3a: To ensure that Flu-FIT runs smoothly, the implementation plans and work flow processes must be reviewed with participating health care providers		
Measures of Accomplishments for Objective 3a: Dissemination of implementation plans, Training sessions, Completion of clinic/pharmacy walk-through		
Activities for Objective 3a	**Person(s) responsible**	**Timeline**
3a.1 Dissemination of implementation plans/workflow processes to implementation partners	Project Coordinator	**Completed by August** Annually
3a.2 Training sessions on work flow processes for participating health care providers	Flu-FIT Champions	**Completed by September** Annually and as needed
3a.3 Pharmacy/clinic walk through two weeks prior to start of Flu-FIT implementation	Flu-FIT Champions	**Completed by mid-September** Annually

Objective 3b: Complete documentation in for >90% of patients aged 50-75 years that received the FIT by March, annually		
Rationale for Objective 3b: Documentation is an integral component of Flu-FIT. Complete documentation increases the likelihood that patients will be followed-up on in a timely fashion.		
Measures of Accomplishments for Objective 2b: Complete documentation in Flu-FIT log, Follow-up log, and Tracking log		
Activities for Objective 2b	**Person(s) responsible**	**Timeline**
3b.1 Documentation of all Flu-FIT encounters in appropriate logs	Clinic/pharmacy staff	**September-March** Ongoing activity
3b.1 Monitoring of all tracking logs to ensure complete documentation	Flu-FIT Champions will be responsible for reviewing these logs for completeness and notifying the appropriate persons to correct any errors during bi-weekly site visits	**September-March** Ongoing, bi-weekly
3b.3 Review of logs with Project Director and Project Coordinator to determine needed changes in workflow processes	Flu-FIT Champions	Ongoing, monthly

Objective 3c: Notification of FIT results to patient's primary care provider (verbal confirmation, fax confirmation) for 100% of patients that completed and mailed their FIT by March, annually		
Rationale for Objective 3c: Flu-FIT relies on referrals to give patients access to further testing if needed. Notifying primary care providers of negative results fosters clinical linkages and good transitions of care		
Measures of Accomplishments for Objective 3c: Notifications documented in Follow-up log		
Activities for Objective 3c	**Person(s) responsible**	**Timeline**
2c.1 Notification of primary care providers.	Clinic/pharmacy staff, Flu-FIT Champions may complete this task if staff need assistance	**September-March** Ongoing activity
2c.2 Documentation of primary care notification	Clinic/pharmacy staff	**September -March** Ongoing
2c.3 Monitoring of all tracking logs to ensure complete documentation	Flu-FIT Champions will be responsible for reviewing these logs for completeness and notifying the appropriate persons to correct any errors during bi-weekly site visits	**September-March** Ongoing, bi-weekly
2c.4 Review of logs with Project Director and Project Coordinator to determine needed changes in workflow processes	Flu-FIT Champions	Ongoing, monthly

Objective 3d: Telephone follow-up reminder two weeks after Flu-FIT encounter (verbal contact, voicemail not sufficient) with >90% of patients that were given a FIT by March, annually		
Rationale for Objective 3d: Studies have found that patients are more likely to complete the FIT if they are reminded. This is a component that must be feasible for staff members in order for Flu-FIT to be successful		
Measures of Accomplishments for Objective 3d: Notifications documented in Follow-up log		
Activities for Objective 3d	**Person(s) responsible**	**Timeline**
2d.1 Reminder phone calls to patients given FIT.	Clinic/pharmacy staff, Flu-FIT Champions may complete this task if staff need assistance	**September-March** Ongoing activity
2d.2 Documentation of reminders	Clinic/pharmacy staff	**September-March** Ongoing
2d.3 Monitoring of all tracking logs to ensure complete documentation	Flu-FIT Champions will be responsible for reviewing these logs for completeness and notifying the appropriate persons to correct any errors during bi-weekly site visits	**September-March** Ongoing, bi-weekly
2d.4 Review of logs with Project Director and Project Coordinator to determine needed changes in workflow processes	Flu-FIT Champions	Ongoing, monthly

Objective 3e: Maintain partnerships and communication with CAG and implementation partners through Years 2 and 3		
Rationale for Objective 3e: The CAG and implementation partners will provide valuable input to optimize the workflow processes for Years 2 and 3		
Measures of Accomplishments for Objective 3e: Meetings completed, attendance, meeting minutes, emails sent		
Activities for Objective 3e	**Person(s) responsible**	**Timeline**
3e.1 Meet with CAG to discuss progress and possible improvements	Project Director	Ongoing, semi-annual
3e.2 Update CAG on progress via email	Project Coordinator	Ongoing, quarterly
3e.3 Meet with implementation partners to discuss progress and possible improvements	Project Director	Ongoing, quarterly
3e.4 Finalization of workflow processes for Years 2 and 3 and dissemination to CAG and implementation partners	Project Director	**Completed by June, annually**

Objective 3f: Increase CRCS rates by >30% from baseline and maintain increased CRCS rate in each practice setting by March, annually		
Rationale for Objective 3f: Increased CRCS rates lead to early detection of colorectal cancer.		
Measures of Accomplishments for Objective 3f: Baseline CRCS rate, CRCS rate of patients that received a FIT during flu season		
Activities for Objective 3f	**Person(s) responsible**	**Timeline**
3f.1 Development of promotional campaign	Project Director, Local Cares, AC Wharton, Dr. Phillip Bowden	**Completed by July 2018**
3f.2 Dissemination of promotional campaign	Local Cares	September-January Annually, starting Year 2
3f.3 Continued implementation of Flu-FIT	Clinic/pharmacy staff	Ongoing

Objective 3g: Increase CRCS knowledge by >50% from baseline and maintain increased CRCS knowledge March, annually		
Rationale for Objective 3g: Patients are more likely to complete CRCS if they know more about the importance of CRCS and the available options		
Measures of Accomplishments for Objective 3f: baseline CRCS knowledge scores, subsequent CRCS knowledge scores		
Activities for Objective 3g	**Person(s) responsible**	**Timeline**
3g.1 Patient education on CRCS at the time of Flu-FIT	Clinic/pharmacy staff	Ongoing
3g.2 Dissemination of promotional campaign	Local Cares	September-January Annually, starting Year 2
3g.3 Bi-weekly site visits to observe patient education and provide feedback on delivery	Flu-FIT Champions	Ongoing, bi-weekly

Objective 3h: Maintain or increase health care provider/staff satisfaction with Flu-FIT		
Rationale for Objective 3h: In order for Flu-FIT to be accepted as a standard of care, health care providers must feel like this project is worthwhile and feasible		
Measures of Accomplishments for Objective 3h: Annual health care provider satisfaction survey scores		
Activities for Objective 3h	**Person(s) responsible**	**Timeline**
3h.1 Meet with implementation partners to discuss program progress and areas for improvement	Project Director	Ongoing, quarterly
3h.2 Meet with clinic/pharmacy staff to discuss program progress, staff concerns, and receive feedback on Flu-FIT processes	Flu-FIT Champions	**September-March** Ongoing, bi-weekly
3h.3 Provide technical assistance to all clinic/pharmacy staff and implementation partners as needed	Project Director, Project Coordinator, Flu-FIT Champions	Ongoing, as needed
3h.4 Improve/change workflow processes based upon feedback from staff and implementation partners	Project Director	Ongoing, as needed

Monitoring/Continuous Quality Improvement

Objective 4: To monitor program progress and improve processes as needed, maintaining communication with between management, staff, and partners throughout the grant period

Objective 4a: Maintain communication between health department staff throughout the grant period		
Rationale for Objective 4a: Communication is key to the success of Flu-FIT and improving processes		
Measures of Accomplishments for Objective 4a: Meetings completed, attendance, meeting minutes, emails sent		
Activities for Objective 4a	**Person(s) responsible**	**Timeline**
4a.1 Monitoring of clinic/pharmacy staff	Flu-FIT Champions	**September-March** Ongoing, bi-weekly
4a.2 Meeting with Flu-FIT Champions to discuss project progress	Project Director, Project Coordinator	**September-March** Ongoing, monthly
4a.3 Conference calls with Flu-FIT Champions to discuss project progress	Project Director, Project Coordinator	**September-March** Ongoing, weekly
4a.4 Meeting with CAG to discuss project progress	Project Director, Project Coordinator	Ongoing, semi-annually
4a.5 Emails updates sent to CAG	Project Coordinator	Ongoing, quarterly
4a.6 Meeting with implementation partners to discuss program progress	Project Director	Ongoing, quarterly

Evaluation and Reporting

Objective 5: To obtain performance measures, implementation measures, and outcome measures in a timely manner throughout the grant period

Objective 5a: Obtain baseline clinic CRCS rates from electronic health records for all clinic sites by March 2017		
Rationale for Objective 5a: Baseline CRCS rates will allow for comparison to CRCS rates after the implementation of Flu-FIT		
Measures of Accomplishments for Objective 5a: Reports completed		
Activities for Objective 5a	**Person(s) responsible**	**Timeline**
5a.1 Obtain clinic data from electronic health record	Software programmer	**Completed by March 2017**

Objective 5b: Obtain baseline pharmacy CRCS rates using the CRCS adherence survey for all pharmacy sites by March 2017		
Rationale for Objective 5b: Baseline CRCS rates will allow for comparison to CRCS rates after the implementation of Flu-FIT		
Measures of Accomplishments for Objective 5b: CRCS adherence scores, reports completed		
Activities for Objective 5b	**Person(s) responsible**	**Timeline**
5a.1 Administration of CRCS adherence survey to patients receiving flu shot aged 50-75 and documentation in to Flu-FIT log	Clinic/pharmacy staff	**Ongoing**
5a.2 Monitoring of Flu-FIT log, data entry, and completion of monthly reports	Flu-FIT Champions	**Ongoing, bi-weekly**

Objective 5c: Obtain CRCS rates during implementation period by May annually		
Rationale for Objective 5c: Implementation CRCS rates will allow for comparison to CRCS rates after the implementation of Flu-FIT		
Measures of Accomplishments for Objective 5c: reports completed, documentation in logs		
Activities for Objective 5c	**Person(s) responsible**	**Timeline**
5c.1 Documentation of Flu-FIT encounters in appropriate tracking logs	Clinic/pharmacy staff	Ongoing
5c.2 Monitoring of Flu-FIT log, data entry, and completion of monthly reports	Flu-FIT Champions	Ongoing
5c.3 Obtaining data from electronic health record	Software programmer	Ongoing, quarterly
5c.4 Data analysis and reports	Biostatistician	Ongoing, monthly

Objective 5d: Obtain CRCS knowledge, patient satisfaction, and health care provider satisfaction scores by May annually		
Rationale for Objective 5d: The results of these surveys will allow the project team to determine if Flu-FIT is improving CRCS knowledge and working to improve patient and health care provider satisfaction		
Measures of Accomplishments for Objective 5d: reports completed, documentation in logs, surveys scored		
Activities for Objective 5d	**Person(s) responsible**	**Timeline**
5d.1 Administration of CRCS knowledge survey	Clinic/pharmacy staff	Ongoing
5d.2 Administration of patient satisfaction survey	Clinic/pharmacy staff, Flu-FIT Champions	Ongoing
5d.3 Administration of health care provider satisfaction survey	Flu-FIT Champions	**Completed by April** Ongoing, annually
5d.4 Scoring of surveys	Flu-FIT Champions	Ongoing

Objective 5f: Perform data analysis quarterly and report measures as appropriate throughout the grant period		
Rationale for Objective 5f: Data analysis is necessary to evaluate the effectiveness and progress of Flu-FIT		
Measures of Accomplishments for Objective 5f: reports completed		
Activities for Objective 5f	**Person(s) responsible**	**Timeline**
5f.1 Data entry	Flu-FIT Champions are responsible for data entry and submitting reports to the Project Coordinator	Ongoing, monthly
5f.2 Data analysis	Biostatistician	Ongoing, quarterly
5f.3 Report performance measures to the funder	Project Director	Ongoing, semi-annually

Appendix G: Flu-FIT Log, Follow-up Log, Tracking Log

FLU-FIT Log /Flu Vaccination Authorization Record

*This form must be **signed** by the vaccine recipient or by the parent, guardian, or other authorized person **on the date the vaccine is administered**.*

I have read or had explained to me the "Influenza Vaccine Information Statement." I have had an opportunity to ask questions which were answered to my satisfaction. I understand the benefits and risks of influenza vaccine and request that it be given to me or to the person for whom I am authorized to make this request. If I am between the ages of 50 and 75 and being offered a FIT/FOBT kit for colorectal cancer screening today, it has been explained to me.

Clinic Staff Initials	Flu Shot Site	Signature	Patient Name / Phone/DOB	FIT Eligible Age 50-75, no FIT/FOBT this year, and no colonoscopy in 10 yrs	FIT Given To Patient Date given
		1.		□ Yes □ No	□ Yes □ No
		2.		□ Yes □ No	□ Yes □ No
		3.		□ Yes □ No	□ Yes □ No
		4.		□ Yes □ No	□ Yes □ No
		5.		□ Yes □ No	□ Yes □ No
		6.		□ Yes □ No	□ Yes □ No
		7.		□ Yes □ No	□ Yes □ No
		8.		□ Yes □ No	□ Yes □ No
		9.		□ Yes □ No	□ Yes □ No
		10.		□ Yes □ No	□ Yes □ No
___ Total FLU Shots Given			Total FIT/FOBT: ____ Eligible ___ Given		

FLU-FIT Follow-up Log

Please provide your initials for any entry in this log. If the patient has a positive FIT result, 1) notify the primary care provider prior to notifying the patient and 2) document the patient in the **tracking log**.

Patient Name/Phone number/DOB	Date FIT given	Date(s) of patient reminder (2 weeks after Flu-FIT encounter)			Date FIT results received /read	FIT result (+ or – or invalid)	Date patient notified of results	Patient's primary care provider	Date primary care provider notified
		Attempt 1	Attempt 2	Attempt 3					
1.									
2.									
3.									
4.									
5.									
6.									
7.									

Tracking Log for Abnormal FIT

Patient Name/Phone number/DOB	Date FIT Completed	Result: pos or neg	Name of PCP (or referral to CCH)	Date PCP Notified or referral to CCH (please specify)	Date colonoscopy scheduled	Date colonoscopy completed
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

Appendix H: CRCS knowledge survey (given to Flu-FIT eligible patients)

Please indicate whether you think each of the following statements is true or false (circle one).

1. People can have colon cancer without having any symptoms.....**True or False**

2. Men have a much higher risk for colon cancer than women.....**True or False**

3. A colon cancer screening test is not a one-time event……**True or False**

4. Beginning at age 50, average-risk individuals should be screened on a regular basis.....

True or False

5. Colon cancer can almost always be prevented or detected early with screening tests.....

True or False

6. People cannot get colon cancer unless it runs in their family.....**True or False**

7. All people's risk for developing colon cancer increases as they age.....**True or False**

8. Once you get colon cancer, there isn't anything you can do about it.....**True or False**

9. How often should you complete a take-home colorectal cancer screening test? (Circle one)

Once every 10 years **Once every three years** **Once every year**

Gender (circle one): Male or Female

What is your race/ethnicity? _____

My age group is (check one):

50 – 59.....□

60 – 69.....□

70 – 79.....□

80 & over.....□

Your highest education is: _____

Adapted from:

Sanderson PR, Weinstein N, Teufel-Shone N, et al. Assessing colorectal cancer screening knowledge at tribal fairs. *Prev Chronic Dis*. 2011; 8(1): A16.

Added questions from Flu-FIT counseling points and talking points.

Appendix I: Patient and Health Provider Satisfaction surveys

Patient satisfaction survey (phone interview)
Check one:

[ ]The patient completed and returned FIT by March
[ ]The patient was given FIT, but did not return FIT by March

Please comment on the following aspects of the Flu-FIT program

1. I feel like I know more about colorectal cancer screening (circle one)
    a. Strongly Agree Agree Disagree Strongly disagree
2. The instructions for the FIT were explained to me clearly (circle one)
    a. Strongly Agree Agree Disagree Strongly disagree
3. I completed the FIT and mailed the FIT (circle one). Yes No

For patients that used the FIT

4. The FIT was easy for me to use (circle one)
    a. Strongly Agree Agree Disagree Strongly disagree
5. I would use the FIT again in the future if it was offered to me (circle one)
    a. Strongly Agree Agree Disagree Strongly disagree
6. I found the reminder phone calls helpful (circle one)
    a. Strongly Agree Agree Disagree Strongly disagree

For patients that did not use the FIT

7. I did not use the FIT because (circle all that apply)
    a. I did not believe it was important
    b. I am "grossed out" by the FIT
    c. I forgot to use it
    d. I am afraid of a positive FIT result
    e. I prefer using a different test
        i. Please specify: Colonoscopy Flexible sigmoidoscopy Other_____

PHARMACY ONLY

8. Have you seen your regular doctor or nurse since you got the flu shot? (circle one)
    Yes No
9. Did you discuss colorectal cancer screening with your doctor or nurse since you got the flu shot? (circle one) Yes No
10. Do you think it is a good idea for community pharmacists to educate patients about colorectal cancer screening when they come for the influenza vaccine?
    Yes No
11. Do you think it is a good idea for community pharmacists to offer patients home colon cancer screening tests when indicated? (circle one) Yes No

Adapted from:
Potter MB, Gildengorin G, Wang Y, Wu M, Kroon L. Comparative effectiveness of two pharmacy-based colorectal cancer screening interventions during an annual influenza vaccination campaign. J Am Pharm Assoc. 2010;50:181-7

Health care provider satisfaction survey

1. What is your profession?
    a. Nursing
    b. Pharmacy
    c. Medicine
2. I believe the FIT is as important or more important than the influenza vaccine (circle one)
    Strongly Agree Agree Disagree Strongly disagree

3. The Flu-FIT program is a worth-while activity (circle one)
    Strongly Agree Agree Disagree Strongly disagree

4. I believe that the Flu-FIT program improved the way FIT is offered in our practice setting (circle one)
    Strongly Agree Agree Disagree Strongly disagree

5. My practice setting has sufficient staff time to implement Flu-FIT (circle one)
    Strongly Agree Agree Disagree Strongly disagree

6. Offering FIT should be a shared responsibility, and not solely the physician's responsibility (circle one)
    Strongly Agree Agree Disagree Strongly disagree

Indicate you r satisfaction with the following aspects of the Flu-FIT program

7. System to offer FIT with influenza vaccine
    Very satisfied Satisfied Unsatisfied Very unsatisfied

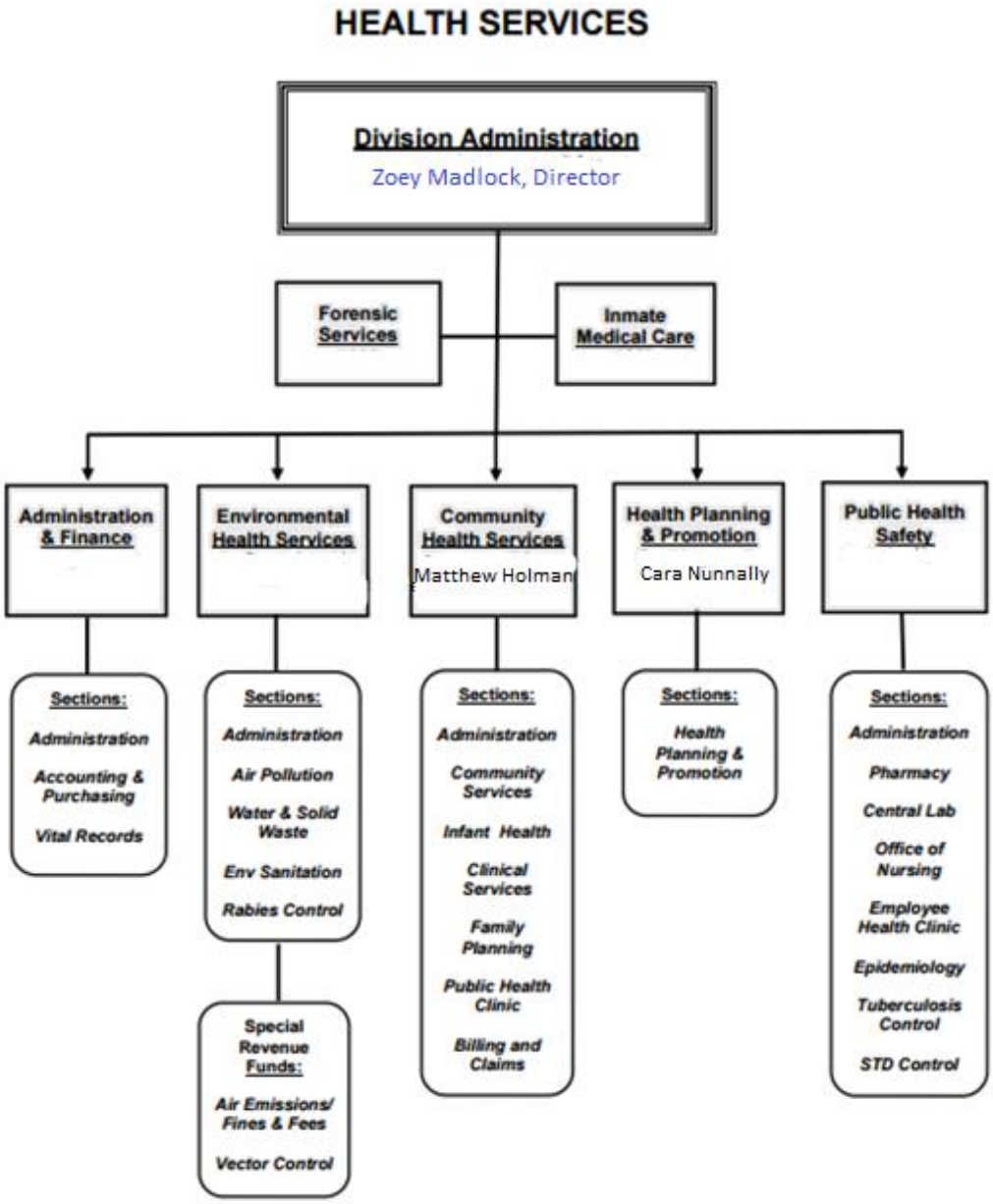
8. Patient education materials provided by the Flu-FIT program
    Very satisfied Satisfied Unsatisfied Very unsatisfied

Sustainability

9. Do you think that Flu-FIT is sustainable in your practice setting?
    a. Yes, sustainable with no changes
    b. Yes, sustainable with minor changes
    c. Yes, sustainable with major changes
    d. No, unsustainable
10. What changes would you make to the program?

Adapted from:
Walsh JM, Gildengorin G, Green L, et al. The Flu-FOBT program in community clinics: durable benefits of a randomized controlled trial. *Health Education Research*. 2012; 27(5): 886-894.

Appendix J: SCHD Organizational Chart

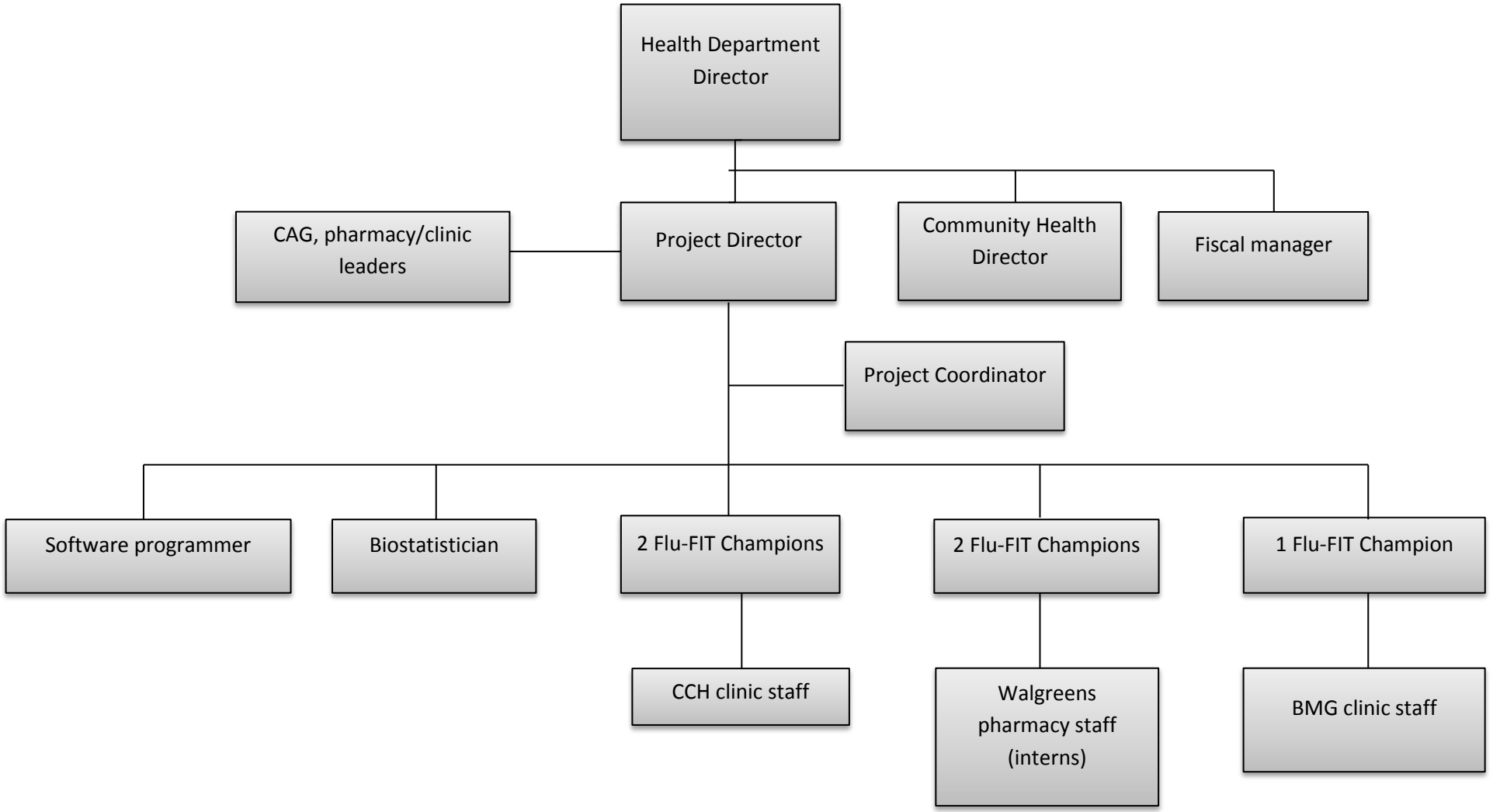


Appendix K: Experience of Shelby County Health Department

Experience of Shelby County Health Department					
Program	**Program goals**	**Population served**	**Program Capacity**	**Activities**	**Outcomes**
Healthy Start Initiatives	Improve maternal and infant health outcomes and eliminate health disparities Reduce infant mortality Empower participants through education, advocacy and connections to community resources.	High risk pre and postnatal teens and women accepted up to 6 months after birth of last child.	240 families	Home visitation Education	During fiscal year 2015 Infant Mortality Rate (IMR) in Shelby County dropped to the lowest level ever recorded (9.2 infant deaths/1,000 live births).
Help Us Grow Successfully (HUGS)	Promote healthy pregnancy to ensure positive birth outcomes Assist clients/families in accessing health care, social and educational services	Pregnant and Postpartum mothers, including pregnant Teens and high-risk pregnant women Children birth through 5 years	175 families	Home visitation Education Referrals	
Freedom from Smoking	Support smoking cessation efforts by highlighting the positive effects of quitting smoking, including improved health and lifestyle.	Adult smokers	10,000 residents (FY16)	Education, counseling, community-based sessions	60% increase in residents reached
Healthy Shelby	Reduction of childhood obesity Control of hypertension in adults Reduction of end of life cost for adults	Infants and children aged to 5 years adults 18-65+	3000 residents	County-wide campaign to encourage physical activity at a designated weekly day and time	TBD

Appendix L: Shelby County Health Improvement Plan Community Partners	
Community partner	**Description**
American Institutes for Research	Conducting and applying the best behavioral and social science research and evaluation towards improving peoples' lives
Backrivercity.com	A Memphis & Shelby County public policy blog, in addition to speaking engagements
Baptist Memorial Health Care	A Health care provider also featuring community outreach through Baptist Healthy Communities
Binghampton Development Corporation	Creating a healthier Binghampton community
Brunswick Community Association	Promoting harmony with neighbors, preserving the integrity of our community, and promoting pride, beautification, and progress in the Brunswick community
Church Health Center	Reclaiming the Church's Biblical commitment to care for our bodies and spirits
City of Memphis Housing and Community Development	To drive community revitalization through a seamless system
Compass Intervention Center	Providing residential and outpatient service to children and adolescents with serious mental health needs; creating a safe, therapeutic, and caring environment for healing to take place
The Corners of Highland Heights	A Community of Shalom focused on community development
DeafConnect of the Mid-South	Uniting the Deaf/Hard of Hearing and Hearing communities through interpreting, advocacy, education, and support
Family Safety Center	Providing one location to coordinate civil, legal, health, and social services for victims of family violence
Food Advisory Council for Memphis and Shelby County	Advance policy and practice in Memphis and Shelby County that strengthen food security and the local food economy
Grow Memphis	Partnering with communities in Memphis and Shelby County to promote a sustainable local food system
Healthy Lifestyle Alliance	Promoting natural, holistic, and healthy practices
Healthy Shelby	Focusing on better health, better care, and lower costs for economic vitality
Le Bonheur Community Health & Well-Being	LCHWB is the community-based health promotion and prevention arm of Le Bonheur Children's Hospital.
Livable Memphis	Supporting Memphis neighborhoods through public policy development and advocacy, organizational capacity building, and community education`
Memphis Child Advocacy Center	Serving children who are victims of sexual and severe physical abuse through prevention, education, and intervention
Memphis Gun Down	Making Memphis streets safer using a five prong, evidence based approach
Memphis Shelby Crime Commission	Coordinates Operation: Safe Community, a comprehensive, coordinated plan to reduce violence and make Memphis-Shelby County one of safest cities of its size in the country.
Memphis VA Medical Center	Providing veterans with quality care, outstanding customer service, education of tomorrow's health care providers, and improvement in health care outcomes
Methodist Le Bonheur Healthcare	An integrated health care delivery system, dedicated to the art of healing through our faith-based commitment to minister to the whole person.
My Brother's Keeper: Inspiring Young Men of Color	In Memphis, the goal is to build upon existing work to improve outcomes in education, healthcare, justice, and employment for young men of color
Physicians for a National Health Program	A non-profit research and education organization supporting single-payer national health insurance
Sanofi	A global healthcare leader focused on patient needs
Shelby County Schools Coordinated School Health	Providing a better coordinated system of health services
St. Francis Hospital	To heal, support, and comfort all whom we serve in the tradition of Catholic healthcare
Tennessee Suicide Prevention Network	Eliminating the stigma of and educating about signs of suicide, ultimately reducing suicide rates in the state of Tennessee
The Kitchen Community	Creating community through food.
United Way of the Mid-South	Improving the quality of life for MidSoutherners by mobilizing and aligning community resources to address priority issues
University of Memphis School of Public Health	Producing the next generation of public health leaders
University of Tennessee Health Science Centers	Promoting health equity across all populations through research, education, and service
YMCA of Memphis & the Mid-South	To put Christian principles into practice through programs that build healthy spirit, mind, and body for all

Appendix M: Project Management



Budget

	Year 1	Year 2	Year 3	Grant Period Total
Personnel	$559,400	$554,225	$581,374	**$1,694,999**
Supplies	$70,800	$127,000	$127,000	**$324,800**
Travel	$1,068	$9,993	$9,993	**$21,054**
Other	$82,765	$168,880	$168,880	**$420,525**
Equipment	$4,900	-	-	**$4,900**
Contractual Costs	$12,800	$12,800	$12,800	**$38,400**
Total	**$1,094,794**	**$1,307,247**	**$1,348,107**	**$3,750,148**

Direct Costs: $2,504,678

F&A Costs: $1,245,470 (50.5%)

Budget Justification

Personnel

Cara Nunnally, MPH, CHES, Project Director- 70% effort

Ms. Nunnally will serve as the Project Director of Flu-FIT. As Project Director, she will be fully responsible and accountable for all aspects of the project throughout the duration of the 3-year grant period and will provide management for all staff and activities involved in the planning, implementation, and evaluation of the proposed Flu-FIT program. She will oversee six Flu-FIT Champions in the implementation and delivery of Flu-FIT in 5 Christ Community Health clinics, 6 Walgreens pharmacies, and 3 BMG Walk-in Clinics. All program materials, reports, and manuscripts will be finalized and approved by Ms. Nunnally. Ms. Nunnally will also be responsible for coordinating monthly meetings with the Flu-FIT committee (Project Director, Project Coordinator, Flu-FIT Champions), the Community Advisory Group, and the representatives from Christ Community Health, Walgreens, and BMG Walk-in Clinics. In addition to her role as Program Director, Ms. Nunnally will serve as back-up when one of the Flu-FIT Champions is unable to conduct an education session or site visit. She has experience

with working multiple organizations including professional organizations and community leaders to coordinate grant activities and will serve as the liaison between project personnel and community partners. Ms. Nunnally looks forward to dedicating the majority of her efforts to Flu-FIT and is confident in the abilities of the Freedom from Smoking project coordinator to manage the bulk of the duties for Freedom from Smoking while she directs Flu-FIT.

TBD, Project Coordinator- 100% effort

The Project Coordinator will be responsible for the day to day management of all resources assigned to the project and will ensure the goals and objectives laid out in the work plan are met, including ensuring all data collection, reports for the project, and abstracts are completed in a timely manner and maintaining the integrity of the program. The Project Coordinator and Cara Nunnally will meet monthly with the Flu-FIT Champions, semi-annually with the Community Advisory Group, and quarterly with representatives from Christ Community Health, Walgreens, and BMG Walk-in Clinics to discuss and monitor implementation progress. The Project Coordinator will prepare reports for the Director, partners, and CAG, using data gathered annually from reported Vital Statistics, TN Department of Public Health, and other reputable sources of data as well as data gathered continuously from program participants and community focus groups. The Program Coordinator must have an MPH with preferably 3 years of experience working with evidence-based programs.

Matthew Holman, MS, SCHD Director of Community Health Services-10% effort

Mr. Holman is the SCHD Director of Community Health Services, which is the largest department in the Health Services Division. This department provides ambulatory, primary, and preventative health care services to a large population through a network of eight SCHD clinics.

These clinics offer services including dental services, immunizations, family planning, nutrition programs, prenatal counseling, and school health programs. Mr. Holman has extensive experience in managing SCHD clinical staff and has valuable insight on day-to-day clinic activities and staff management. He will serve in an advisory capacity to the Project Director.

Zoey Madlock, MAT, Director of the SCHD-6% effort

Ms. Madlock has served as the Director of the SCHD for over 20 years and has extensive involvement in various community organizations and partnerships. She has valuable connections in the community as well as existing connections with CCHC and BMG. She will serve in an advisory capacity to the Project Director

TBD, Flu-FIT Champions-100% effort

Six Flu-FIT Champions will be hired to oversee the 14 practice sites. Each Flu-FIT Champion will be assigned to oversee 2-3 practice sites each. They will be responsible for carrying out the day-to-day activities laid out in the work plan, namely training, fidelity monitoring, data collection, and data entry. They will send the Project Coordinator survey responses and an updated implementation checklist monthly. Flu-FIT Champions will serve as members of the Flu-FIT committee, which meets monthly to discuss the progress of the program and address any issues. Flu-FIT Champions must have an MPH or CHES, with at least 2 years of research experience.

TBD, Statistician-25% effort

A statistician from the University of Memphis College of Public Health will perform all data analyses on a monthly basis. The statistician will receive the data collected by the Flu-FIT

Champions and work closely with the Project Director to complete the requested analyses. He/she will also track changes in the county's BRFSS survey over the grant period.

Fiscal Manager-10% effort

The fiscal manager in the SCHD will assist the Project Director in managing the finances over the course of the grant period.

Fringe benefits

The fringe benefit rate on this grant is 21.55%.

Supplies

Supplies are needed to support the implementation of Flu-FIT, including reports and educational materials. These supplies include: copy paper, printer paper, printer cartridges, binders, tabs, FIT kits with prepaid envelopes, markers, post-its, pens and notepads. Supplies for the delivery of the influenza vaccine are not required since those are available in the clinic and pharmacy settings regularly. Fewer kits are needed in Year 1 since fewer patients will be reached during the pilot period.

	Year 1	**Year 2**	**Year 3**
Office supplies	$2,000	$2,000	$2,000
Fit Kits	68,800 (2752 patients, $25 kit)	$125,000 (6400 patients, $25 kit)	$125,000 (6400 patients, $25 kit)
Total	$70,800	$127,000	$127,000

Equipment

Laptops for all six Flu-FIT Champions and the Project Coordinator to facilitate data entry and staff training. $700 x 7 employees= $4,900, Year 1 only.

Travel

In-state travel

We request funding for project staff to travel to participating CCH clinics, BMG clinics, and Walgreens pharmacies for site visits, training sessions, and the provision of technical assistance. Fewer miles will be traveled during Year 1 since fewer sites will be involved. 1,857 total miles in Year 1 at $0.575 federal mileage reimbursement rate; total $1,068 for Year 1.

4,320 total miles at $0.575 federal mileage reimbursement rate per year; total $2,484 each year x 2 years = $4,968.

Out of State Travel

Per RFA language regarding presentation of our findings at a minimum of two national conferences, we request travel funds for three team members (e.g. Ms. Nunnally, Project Coordinator, Flu-FIT Champions) to attend one conference during each year of the grant to present findings from the proposed project. Proposed conferences include the CDC Cancer Survivorship Conference (Spring 2019 or Spring 2020), CDC cancer grantees' meeting (held annually), American Public Health Association (held annually each fall), and the American Association for Cancer Education (held annually each spring), among other conference options.

2 nights lodging x $250/night= $500
Airfare= $400
Registration= $350
3 days per diem x $75/day= $225

Ground transportation= $100
Baggage= $50
Parking at airport= $50Total= $1,675 each year x 7 team members = $5,025 per year

	Year 1	**Year 2**	**Year 3**
In state	$1,068	$4,968	$4,968
Out of state		$5,025	$5,025
Total	$1,068	$9,993	$9,993

Contractual Costs

Software Programmer

In order to obtain data from clinic electronic medical records, we will contract the services of a software programmer to run reports for all clinic sites on a quarterly basis. The Program Director will work closely with the software programmer to discuss data needs. 4 reports per yearx 8 sitesx 8 hours=32 reports, programmer, $50 per hour, $12,800 per year

Other

Participation Stipend

We are requesting $9,000 per Flu-FIT practice site for incentivizing the 5 CCH clinics, 6 Walgreens pharmacies, and 3 BMG clinics that committed to implementing Flu-FIT for the grant period. The pilot Flu-FIT awarded each participating facility $5,000 per year during the grant period for program implementation alone; clinic/pharmacy staff did not participate in data collection or survey distribution. In addition, the research team did the majority of the patient follow-up and education, especially in the pharmacy setting. Our implementation of Flu-FIT will require more clinic/pharmacy staff involvement to and we feel this increased incentive is justified. As part of their involvement in the project, the healthcare facilities will pledge to implement Flu-FIT, including the necessary patient education, patient follow-up, documentation,

and survey distribution. Participating facilities also agree to the periodic collection of process evaluation measures and meetings with staff. The monetary incentive helps to offset the costs of participation in terms of administrative support, supplies, and data collection/reporting. The monetary incentive may also be used to for the development of setting-specific promotional materials (posters, banners, brochures). For pharmacies, this incentive may also be used to afford additional "floater" pharmacists during high volume hours to ensure that Flu-FIT does not interfere with the day-to-day pharmacy activities. Based on data collected from the practice sites, our goal is to refine workflow processes to ensure the efficient and effective implementation of Flu-FIT in existing systems.

Patient incentive for survey participation

We are requesting $5 Visa gift cards to incentivize patients for completing the pre and post surveys for CRCS knowledge. Patients will receive an additional $5 Visa gift card if they also complete the patient satisfaction survey six months after the Flu-FIT encounter. During Year 1, fewer patients will be reached (2752 patients). We expect to offer the surveys to 6,400 patients during Years 2 and 3.

Year 1: 2,752 patients, $27,520

Years 2 and 3: 6,400 patients per year, $40,000 per year

Patient travel assistance

We are requesting $15 gas cards to offer to patients requiring travel assistance for the appropriate follow-up in the event of an abnormal FIT result. We expect approximately 3% of Flu-FIT patients to require follow-up by a primary care provider.

Year 1: 2,752 reached with Flu-FIT, 3% have positive results=83 patients, $1,245 per year

Years 2 and 3: 6,400 reached with Flu-FIT, 3% have positive results= 192 patients per year. $2,880 per year

	Year 1 (2752 patients)	**Year 2 (6400 patients)**	**Year 3 (6400 patients)**
Patient travel	$1,245	$2880	$2880
Survey incentive	$27,520	$40,000	$40,000
Participation stipend	$54,000	$126,000	$126,000
Total	$82,765	$168,880	$168,880